



## ARIZONA DEPARTMENT OF HEALTH SERVICES

POLICY & INTERGOVERNMENTAL AFFAIRS

August 18, 2021

*Sent Via Electronic Mail*

Timothy C. Martin

Re: Response-August 16, 2021 Public Records Request

Dear Mr. Martin:

On behalf of the Arizona Department of Health Services ("ADHS"), I am responding to your August 16, 2021 public records request (the "Request"). In your Request, you ask for communicable disease related information, specifically records "describing the isolation of a SARS-CoV-2 virus, directly from a sample taken from a diseased patient, where the patient sample was not first combined with any other source of genetic material (i.e. monkey kidney cells aka Vero cells; liver cancer cells, lung cells from a lung cancer patient)."

In response to your Request, ADHS does not have any records "describing the isolation of a SARS-CoV-2 virus, directly from a sample taken from a diseased patient, where the patient sample was not first combined with any other source of genetic material." Please note that available de-identified COVID-19 data, including case data, may be reviewed at: <https://www.azdhs.gov/covid19/data/index.php>. You may also wish to check with the Centers for Disease Control and Prevention for information that may be useful to you. See <https://www.cdc.gov/coronavirus/2019-ncov/index.html>.

In addition, even if ADHS had records responsive to your Request, A.R.S. § 36-664(A) states: "[a] person who obtains **communicable disease related information** in the course of providing a health service or obtains that information from a health care provider pursuant to an authorization **shall not disclose or be compelled to disclose** that information except as authorized by state or federal law...." (Emphasis added). See also A.R.S. §§ 36-661(5), (14), (21), 36-664(C), 36-665 and 36-666(A)(2) (it is a class 3 misdemeanor to disclose communicable disease related information in violation of A.R.S. Title 36, Chapter 6, Article 4); May 29, 2020 Under Advisement Ruling issued in Maricopa County Superior Court Case No. CV2020-005385; January 29, 2021 Minute Entry issued in Maricopa County Superior Court Case No. CV2020-012030.

Douglas A. Ducey | Governor Cara M. Christ, MD, MS | Director

---

150 N. 18th Ave., Suite 200, Phoenix, AZ 85007-2670 P | 602-542-1020 F | 602-364-1150 W | [azhealth.gov](http://azhealth.gov)  
*Health and Wellness for all Arizonans*

53647409.1

Timothy C. Martin  
August 18, 2021  
Page Two

Further, A.R.S. § 36-784(C) states: “[a]ny medical information or other information from which a person might be identified that is received by the department or local health authority in the course of an enhanced surveillance advisory is **confidential and is not available to the public.**” (Emphasis added). *See also* A.R.S. §§ 36-136(I)(11),<sup>1</sup> 36-785(C) (information from which a person might be identified that is received by ADHS in the course of an enhanced surveillance advisory is confidential and not available to the public), 36-790(A) (requiring ADHS to maintain the confidentiality of the medical information and personal identifiers received), May 29, 2020 Under Advisement Ruling issued in Maricopa County Superior Court Case No. CV2020-005385; January 29, 2021 Minute Entry issued in Maricopa County Superior Court Case No. CV2020-012030.

Based on the foregoing, ADHS does not have the records you seek, and in the event your Request seeks more than the publicly available COVID-19 data accessible through the aforementioned ADHS webpage, ADHS cannot make those records available to you as a matter of law. Either way, ADHS is unable to fulfill your Request.

Sincerely,



Stephanie Elzenga, Administrative Counsel  
Division of Policy and Intergovernmental Affairs, Administrative Counsel and Rules

cc: Greg Falls and Craig Morgan, Sherman and Howard

---

<sup>1</sup> The Arizona Administrative Code (“A.A.C.”) supports the foregoing legal interpretation. A.A.C. R9-1-301(6) and -303(D) require ADHS to “ensure that public health records disclosed pursuant to a public records request are de-identified” pursuant to 45 C.F.R. 164.514(b)(2)(i). *See* [https://apps.azsos.gov/public\\_services/register/2020/25/contents.pdf](https://apps.azsos.gov/public_services/register/2020/25/contents.pdf).

Douglas A. Ducey | Governor    Cara M. Christ, MD, MS | Director

---

## Fw: FOIA Request

---

James Smith <[REDACTED]> Mon, Aug 9, 2021 at 2:31 PM  
To: [REDACTED] Christine Massey <cmssyo@gmail.com>

---

From: Reginald Rogers <[Reginald.Rogers@arkansas.gov](mailto:Reginald.Rogers@arkansas.gov)>  
Sent: Monday, August 9, 2021 1:28 PM  
To: James Smith <[REDACTED]>  
Cc: Laura Shue (ADH) <[Laura.Shue@arkansas.gov](mailto:Laura.Shue@arkansas.gov)>; Charles Thompson (ADH) <[Charles.Thompson@arkansas.gov](mailto:Charles.Thompson@arkansas.gov)>; Brian Nichols (ADH) <[Brian.Nichols@arkansas.gov](mailto:Brian.Nichols@arkansas.gov)>; S.Craig Smith <[Stephan.Smith@arkansas.gov](mailto:Stephan.Smith@arkansas.gov)>; Michael St. Clair <[Michael.StClair@arkansas.gov](mailto:Michael.StClair@arkansas.gov)>; Tressa Williams (ADH) <[Tressa.Williams@arkansas.gov](mailto:Tressa.Williams@arkansas.gov)>  
Subject: FW: FOIA Request

Attached are 2 emails from UAMS which refer to projects on looking for COVID 19 in wastewater. I have been informed by that the ADH Public Health Laboratory (PHL) does not purify the SARS-CoV-2 virus. I have not been provided with any reports or studies on "purification" of the Covid-19 virus. Thank you.

Reginald A. Rogers  
Deputy General Counsel  
Arkansas Department of Health  
4815 W. Markham St., Slot 31  
Little Rock, Arkansas 72205-3867

Phone : (501) 661 - 2609  
Cell : (501) 944 - 2962  
Fax : (501) 661 - 2357  
Email: [reginald.rogers@arkansas.gov](mailto:reginald.rogers@arkansas.gov)



---


From: James Smith <[REDACTED]>  
Sent: Sunday, August 8, 2021 10:14 PM  
To: [coronavirus@arkansas.gov](mailto:coronavirus@arkansas.gov); Reginald Rogers <[reginald.rogers@arkansas.gov](mailto:reginald.rogers@arkansas.gov)>  
Cc: [REDACTED]



Subject: FOIA Request

## Arkansas FOIA Request

James W. Smith, DC



08/08/2021

Reginald Rogers

Custodian of Records

Arkansas Department of Health

4815 W. Markham St.

Little Rock, AR 72205

Dear Reginald Rogers:

Under the Arkansas Freedom of Information Act § 25-19-101 et seq., Description of Requested Records: All studies and/or reports in the possession, custody or control of the Arkansas Department of Health describing the purification of any "COVID-19 virus" (including "B.1.1.7", "B.1.351", "P.1" and any other "variant") (via maceration, filtration and use of an ultracentrifuge; also referred to at times by some people as "isolation"), directly from a sample taken from a diseased human, where the patient sample was not first combined with any other source of genetic material (i.e. monkey kidney cells aka Vero cells; fetal bovine serum). Please note that I am not requesting studies/reports where researchers failed to purify the suspected "virus" and instead: cultured an unpurified sample or other unpurified substance, and/or performed an amplification test (i.e. a PCR test) on all the RNA from a patient sample or from a cell culture, or on genetic material from any unpurified substance, and/or sequenced the total RNA from a patient sample or from a cell culture or from any unpurified substance, and/or produced electron microscopy images of unpurified things. For further clarity, please note I am already aware that according to virus theory a "virus" requires host cells in order to replicate, and I am not requesting records describing the replication of a "virus" without host cells. Further, I am not requesting records that describe a suspected "virus" floating in a vacuum; I am simply requesting records that describe its purification (separation from everything else in the patient sample, as per standard laboratory practices for the purification of other small things). Please also note that my request is not limited to records that were authored by the CDC or ATSDR or that pertain to work done at/by the CDC or ATSDR. Rather, my request includes any record matching the above description, for example (but not limited to) any published peer-reviewed study authored by anyone, anywhere, ever that has been downloaded or printed and relied on as evidence of a disease-causing "virus". If any records match the above description of requested records and are currently available to the public elsewhere, please provide enough information about each record so that I may identify and access each one with certainty (i.e. title, author(s), date, journal, where the public may access it). Please provide URLs where possible.

If there are any fees for searching or copying these records, please inform me if the cost will exceed \$100. However, I would also like to request a waiver of all fees in that the disclosure of the requested information is in the public interest and will contribute significantly to the public's understanding of the isolation of purified



SARS-COV-2. This information is not being sought for commercial purposes.


The Arkansas Freedom of Information Act requires a response within three business days. If access to the records I am requesting will take longer, please contact me with information about when I might expect copies or the ability to inspect the requested records.

If you deny any or all of this request, please cite each specific exemption you feel justifies the refusal to release the information and notify me of the appeal procedures available to me under the law.

Thank you for considering my request.

Sincerely,

Dr. James W. Smith



----- Forwarded message -----

From: David Ussery <daveussery@gmail.com>

To: SUSAN HANRAHAN <hanrahan@astate.edu>, Jake Rice <jrice@jonesborocwl.org>

Cc: Atul Kothari <Atul.Kothari@arkansas.gov>, "Robeson, Michael" <MRobeson@uams.edu>

Bcc:

Date: Wed, 24 Feb 2021 22:22:20 +0000

Subject: Re: Water samples

Hi Susan, Jake,

Thanks for your email. I'll attach a PDF of my talk last week, along with a PDF of an NIH U01 grant that I wrote for looking at Covid-19 in Arkansas wastewater. Unfortunately, that grant didn't get funded, but I'm hoping that I can reuse some of the same ideas in other proposals. For example, the CDC is funding some projects along these lines, I think. We are thinking about applying for a small bit of internal funding to explore a project with ConwayCorp - they've already been looking for Covid-19 in their wastewater for several months now (in collaboration with a colleague in Tacoma, Washington). We're hoping to do some of the analysis locally, but are trying to figure out the logistics of this, in terms of biosafety approval for the labs. Perhaps we could set up a time to discuss this some more sometime? As a general rule, Fridays are free for me.

With best wishes,

Dave

> On Feb 24, 2021, at 11:08, SUSAN HANRAHAN <hanrahan@astate.edu> wrote:

>

> Dave, I am Susan Hanrahan, Dean of the College of Nursing and Health Profession at Arkansas State University. I listened to your ARA presentation last week and when you made a call for "water samples", I listened. I sit on the board of City Water and Light in Jonesboro (water, wastewater and electricity). I spent a little time with our CEO, Jake Rice, to explain your coronavirus quest through water treatment samples. I am hooking both of you up so you can better explain your project to Jake and he can see if CWL can be of any value to your research. Good luck and thanks for your good work! Susan

----- Forwarded message -----

From: "Ussery, David W" <DWUssery@uams.edu>

To: Atul Kothari <Atul.Kothari@arkansas.gov>

Cc:

Bcc:

Date: Thu, 7 Jan 2021 17:33:21 +0000

Subject: quick question...

Hi Atul,

I've read that CDC is investing money in sequencing COVID-19, to keep track of the more virulent UK strain, for example.

Do you know anything about this?

I woke up this morning thinking about a grant for the ARA (Arkansas Research Alliance). It's due on the 11th of January (Monday), and I was thinking about asking for \$100,000, for sequencing COVID-19 from wastewater in Conway, Arkansas. What do you think of this? Would you be willing to help? There's a pretty good chance it'll get funded - last year they funded 12 grants out of 12 proposals (!).

p.s., still waiting to hear back from the NIH on my U01 grant (see attached). It was SUPPOSED to have started first of December, but with all the budget problems (we almost had a government shutdown a few weeks ago!) - the NIH program managers are just now going their budgets - HOPE to hear in the next week or two on that one - it'd be great if we got it, of course! I think it was a good proposal - and I see that Arkansas is now back in the 'top10', in terms of number of cases per 100,000 (see screenshot from this morning's paper)

With best wishes,

Dave

---

Professor David W. Ussery, PhD

Helen Adams & the Arkansas Research Alliance Chair in Biomedical Informatics  
University of Arkansas for Medical Sciences

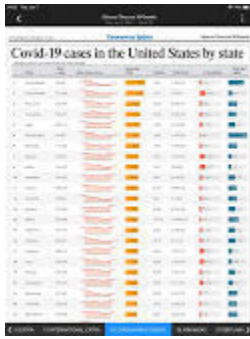
---

---

Confidentiality Notice: This e-mail message, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply e-mail and destroy all copies of the original message.

---

**8 attachments**



7113E4C0-B89A-4C56-B842-A7D9D4526DE8\_1\_101\_o.jpeg  
256K

 **ARA\_Project\_Scope\_17Feb2021\_f-compressed.pdf**  
5817K

 **4492952\_Egrant-compressed.pdf**  
3457K

 **Re: Water samples.eml**  
12706K

 **4492952\_Egrant-compressed.pdf**  
3336K

 **ATT00001.htm**  
2K

 **ATT00002.htm**  
2K

 **quick question....eml**  
4938K



**From:** CDPH Public Records Portal [cdph@govqa.us](mailto:cdph@govqa.us)  
**Subject:** California Public Records Request :: P013439-080421  
**Date:** August 18, 2021 at 10:23 PM  
**To:** [kimleonoudakis@yahoo.com](mailto:kimleonoudakis@yahoo.com)

---



August 18, 2021

RE: Public Records Act Request, Reference Number P013439-080421

Dear Kim Leonoudakis,

On August 04, 2021, the California Department of Public Health (CDPH) received your request for the following records under the Public Records Act:

*1. describing the isolation of the of the SARS-COV-2 (COVID-19) virus including any "variants" that allegedly causes the disease referred to as COVID-19 in the United States, directly from a sample taken from a diseased patient, where the patient sample was not first combined with any other source of genetic material (i.e., monkey kidney cells, aka vero cells; liver cancer cells; fetal bovine serum).*

*2. describing how this alleged new variant referred to as Delta relates to the alleged "SARSCOV-2 (COVID-19) virus" including any analysis or investigation into this alleged new variant, Delta.*

*3. I am not requesting records where "isolation of a "SARS-COV-2" refers instead only to:*

- the culturing of something: and/or*
- the performance of an amplification test (i.e. a PCR test), and/or*
- the sequencing of something, or*
- the fabrication of a genome.*

After reviewing your initial request, we were unable to identify the requested information based upon the description. Accordingly, on Aug 12, 2021, we requested additional information from you in order to clarify certain portions of your request so that we may have provided responsive records, if any. You provided the clarifying information on Aug 15, 2021.

After reviewing your initial request, and subsequent clarifying information, CDPH has determined it is not in possession of records that are responsive to the request.

Thank you,

Chloe Guidera

To monitor the progress, update this request, or download responsive records, please log into the [Public Records Center](#).

---

**Fwd: California Public Records Request :: P013542-081421**

---

Robin [REDACTED]  
To: Christine Massey <cmssyc@gmail.com>

Tue, Aug 24, 2021 at 4:30 PM

Hi Christine!

I just received the response from the California Department of Public Health. It is not in a PDF format. I hope you will still be able to add it to your list. Of course they have "no records". If you need anything else, please let me know.

Sincerely,

Robin [REDACTED]

----- Forwarded message -----

From: CDPH Public Records Portal <cdph@govqa.us>  
Date: Tue, Aug 24, 2021, 1:24 PM  
Subject: California Public Records Request :: P013542-081421  
To: [REDACTED]



RE: Public Records Reference # P013542-081421

Dear Robin [REDACTED]

On August 14, 2021, the California Department of Public Health (CDPH) received your request for records under the Public Records Act (PRA) wherein you requested the following:

*This is a request for general records, under the California Public Records Act § 6250 et seq.*

**Description of Requested Records:**

*All studies and/or reports in the possession, custody or control of the California Department of Public Health describing the purification (i.e. via filtration and ultra-centrifugation) of any "COVID-19 virus" (aka "SARS-COV-2", including any alleged "variants" i.e. "B.1.1.7", "B.1.351", "P.1") directly from a sample taken from a diseased human, where the patient sample was not first combined with any other source of genetic material (i.e. monkey kidney cells aka Vero cells; fetal bovine serum).*

*Please note that I am not requesting studies/reports where researchers failed to purify the suspected "virus" (separate the alleged "virus" from everything thing else in the patient sample) and instead:*

*- Cultured an unpurified sample or other unpurified substance, and/or performed an amplification test (i.e. a PCR test) on the total RNA from a patient sample or from a cell culture, or on genetic material from any unpurified substance, and/or*

*-Fabricated a genome based on PCR-detected sequences in the total RNA from a patient sample or from a cell*

*culture or from any unpurified substance, and/or*

*-Produced electron microscopy images of unpurified things in a cell culture.*

#### *Clarification of Request*

*For further clarity, please note I am already aware that according to virus theory a "virus" requires host cells in order to replicate, and I am not requesting records describing the replication of a "virus" without host cells.*

*Further, I am not requesting private patient information, or records that describe a suspected "virus" floating in a vacuum; I am simply requesting records that describe its purification (i.e. separation from everything else in the patient sample, as per standard laboratory practices for the purification of other very small things).*

*Please note that my request includes any study/report matching the above description, for example (but not limited to) any published peer-reviewed study authored by anyone, anywhere.*

*If any records match the above description of requested records and are currently available in the public domain, please provide enough information about each record so that I may identify and access each one with certainty (i.e. title, author(s), date, journal, where the public may access it). Please provide URLs where possible.*

*If there are any fees for searching or copying these records, please inform me if the cost will exceed \$5. However, I would also like to request a waiver of all fees in that the disclosure of the requested information is in the public interest and will contribute significantly to the public's understanding of "COVID-19". This information is not being sought for commercial purposes.*

*The California Public Records Act requires a response within ten business days. If access to the records I am requesting will take longer, please contact me with information about when I might expect copies.*

*If you deny any or all of this request, please cite each specific exemption you feel justifies the refusal to release the information and notify me of the appeal procedures available to me under the law.*

#### *Format*

*Electronic files conveyed to me via email, preferably in PDF format; I do not wish for anything to be shipped to me.*

CDPH has completed a diligent search and has determined that it is not in possession of records that are responsive to your request. For this reason, this concludes CDPH's response to your request, which will now be closed.

Sincerely,

Taylor St. Mary  
AGPA  
CID/DCDC

To monitor the progress, update this request, or download responsive records, please log into the [Public Records Center](#).





Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30333  
December 30, 2020

*SENT VIA EMAIL*

[REDACTED]  
Dear Mr. [REDACTED]

This letter is our final response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of December 20, 2020, assigned #21-00394-FOIA, for:

All records in the possession, custody or control of The Centers for Disease Control (CDC) describing the isolation of a SARS-COV-1 viruses well as any of the other common cold associated coronaviruses, directly from a sample taken from a diseased patient, where the patient sample was not first combined with any other source of genetic material (i.e. monkey kidney cells aka vero cells; lung cells from a lung cancer patient).

Please note that I am using "isolation" in the every-day sense of the word: the act of separating a thing(s) from everything else. I am not requesting records where isolation of SARS-COV-1 or any of the other common cold associated coronaviruses refers instead to:

\*

\*

\*

the culturing of something, \* or the performance of an amplification test (i.e. a PCR test), \* or the sequencing of something.

\*

Please also note that my request is not limited to records that were authored by the CDC or that pertain to work done by The CDC. My request includes any sort of record, for example (but not limited to any published peer-reviewed study that the CDC has downloaded or printed.

If any records match the above description of requested records and are currently available to the public elsewhere, please provide enough information about each record so that I may identify and access record with certainty (i.e. title, author(s), date, journal, where the public may access it).

A search of our records failed to reveal any documents pertaining to your request.

You may contact our FOIA Public Liaison at 770-488-6277 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at [ogis@nara.gov](mailto:ogis@nara.gov); telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

Page 2—

If you are not satisfied with the response to this request, you may administratively appeal by writing to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201. You may also transmit your appeal via email to [FOIARequest@psc.hhs.gov](mailto:FOIARequest@psc.hhs.gov). Please mark both your appeal letter and envelope "FOIA Appeal." Your appeal must be postmarked or electronically transmitted by Tuesday, March 30, 2021.

You may wish to visit the following link for publications regarding the isolation of SARS-CoV-1 and other human coronaviruses: <https://pubmed.ncbi.nlm.nih.gov/>.

Sincerely,



Roger Andoh  
CDC/ATSDR FOIA Officer  
Office of the Chief Operating Officer  
Phone: (770) 488-6399  
Fax: (404) 235-1852

#21-00394-FOIA



March 1, 2021

***SENT VIA EMAIL***



This letter is in response to your February 21, 2021, email regarding our response dated February 21, 2021, to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of January 6, 2021, assigned #21-00464-FOIA, for the following information:

All records in the possession, custody or control of CDC/ATSDR describing the isolation of a SARS-COV-2 virus, directly from a sample taken from a diseased patient, where the patient sample was not first combined with any other source of genetic material (i.e. monkey kidney cells aka vero cells; lung cells from a lung cancer patient).

Please note that I am using 'isolation' in the every-day sense of the word: the act of separating a thing(s) from everything else. I am not requesting records where 'isolation of SARS-COV-2' refers instead to:

- the culturing of something, or
- the performance of an amplification test (i.e. a PCR test), or
- the sequencing of something.

Please also note that my request is not limited to records that were authored by CDC/ATSDR or that pertain to work done by CDC/ATSDR. My request includes any sort of record, for example (but not limited to) any published peer-reviewed study that CDC/ATSDR has downloaded or printed.

If any records match the above description of requested records and are currently available to the public elsewhere, please provide enough information about each record so that I may identify and access each record with certainty (i.e. title, author(s), date, journal, where the public may access it).

We received your clarification scope dated January 11, 2021, which provided the following information:

This is not a complex question. I have already received a response from the CDC on this topic in November. The ONLY reason I have resubmitted is because I inquired with LaShanda ([LSchofield@cdc.gov](mailto:LSchofield@cdc.gov)) who was my previous case manager. She advised that I resubmit my question due to the following claim by the CDC:

<https://www.cdc.gov/coronavirus/2019-ncov/lab/grows-virus-cell-culture.html>



Since the above article is dated December and I received a response in Nov, then there should only be the analysis of the content on that page.

Therefore, I am rejecting the 'complicated' claim and expect a response within 30 business days. If not, I will submit with the Ombudsman right away.

You provided us the following written summary dated February 2, 2021:

I will respond fully to the FOIA response in this email. I don't remember exactly what I said in my voicemail so I will articulate the entire issue here.

### **Summary**

In this section I will summarize my points. Sections after this summary are just my detailed analysis of the references in the 21-00464-FOIA response.

- My FOIA requests the real isolation (separation of SARS-COV-2 from everything else also known as purification) and has not been answered by 21-00464-FOIA
- 21-00464-FOIA has requested all records that demonstrate the isolation (separation / purification) of SARS-COV-2 since Nov 2020
- The response to 21-00464-FOIA did not produce any records for the isolation (separation / purification) of SARS-COV-2
- I am seeking a new response to my initial inquiry of the isolation (separation / purification) of SARS-COV-2 between Nov 2020 and present.
- I do not want any records that do not match my initial request (See attached.).

On February 21, 2021, the subject matter expert (SME) stated the following:

The requester specifies that the requester would like documents related to isolation, defined by the requester as “separation of SARS-COV-2 from everything else also known as purification”; viruses need cells to replicate, and cells require liquid food, so this specific component of the request is outside of what is possible in virology. However, the SARS-CoV-2 virus may be isolated from a human clinical specimen by culturing in cell culture, as indicated in the previous round of response and produced below.

Evidence of SARS-CoV-2 infection can be found in a study entitled, [Pathology and Pathogenesis of SARS-CoV-2 Associated with Fatal Coronavirus Disease](#), which includes electron microscopy images of SARS-CoV-2 in infected lung and upper airway tissues as well as staining of lung and upper airway tissues using an antibody against SARS-CoV-2. The specimens analyzed in this study were from patients with common signs and symptoms associated with COVID-19, including fever, cough, and shortness of breath. All patients had abnormal findings on chest radiographs. There are other similar studies publicly available online. To aid in locating other related studies, please see the articles suggested in the "Similar Articles" and "Cited by" section on the manuscript's [PubMed entry \(https://pubmed.ncbi.nlm.nih.gov/32437316/\)](#).

The SARS-CoV-2 virus may be isolated from human clinical specimens by culturing in cells. In January 2020, CDC [isolated the SARS-CoV-2 virus \(https://wwwnc.cdc.gov/eid/article/26/6/20-0516\\_article\)](#) from a clinical specimen from the first confirmed case of COVID-19 in the United States. There are other similar studies published describing the isolation and characterization of SARS-CoV-2 from human clinical specimens. To aid in locating other related studies, please see the articles suggested in the "Similar Articles" and "Cited by" section on the manuscript's [PubMed entry \(https://pubmed.ncbi.nlm.nih.gov/32160149/\)](#). There are also [several publications](#) documenting SARS-CoV-2 infection and transmission among pre-symptomatic and asymptomatic individuals ([https://pubmed.ncbi.nlm.nih.gov/32364890/](#)).

For information about the SARS-CoV-2 genome sequence, see the NIH GenBank website (<https://www.ncbi.nlm.nih.gov/genbank/sars-cov-2-seqs/>), which includes over 44,000 sequences as of December 7, 2020.

On February 21, 2021, you requested the following information:

Can you please clarify if you have any records of the separation of SARS-COV-2 from everything else (known as isolation and purification)? A simple yes or no will do regarding the answer. Please use the Merrian-Webster dictionary's common definition of [isolation](#). I will provide the definitions below:

### [isolation](#)

**isolation** noun



Save Word

iso-la-tion | \ ˌɪ-sə-ˈlā-shən also ˌi- \

#### Definition of *isolation*

: the action of [isolating](#) : the condition of being [isolated](#)

### [Isolated](#)

**isolated** adjective



Save Word

iso-lat-ed | \ ˈɪ-sə-,lā-təd also ˈi- \

#### Definition of *isolated*

**1** : occurring alone or once : [UNIQUE](#)

**2** : [SPORADIC](#)

### [Isolate](#)

**isolate** verb



Save Word

iso-late | \ ˈɪ-sə-,lāt also ˈi- \

**isolated; isolating**

#### Definition of *isolate* (Entry 1 of 3)

*transitive verb*

**1** : to set apart from others

also : [QUARANTINE](#)

**2** : to select from among others

*especially* : to separate from another substance so as to obtain pure or in a free state

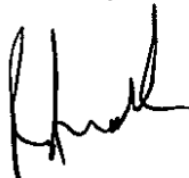
**3** : [INSULATE](#)

The SME states the following:

The definition of “isolation” provided in the request is outside of what is possible in virology, as viruses need cells to replicate, and cells require liquid food. However, the SARS-CoV-2 virus may be isolated from a human clinical specimen by culturing in cell culture, which is the definition of “isolation” as used in microbiology, and as indicated in the previous round of response in the resources provided.

If you need any further assistance or would like to discuss any additional aspect of the records provided please contact either our FOIA Requester Service Center at 770-488-6399 or our FOIA Public Liaison at 770-488-6277.

Sincerely,

A handwritten signature in black ink, appearing to read 'Roger Andoh', with a stylized, cursive script.

Roger Andoh  
CDC/ATSDR FOIA Officer  
Office of the Chief Operating Officer  
Phone: (770) 488-6399  
Fax: (404) 235-1852

21-00464-FOIA



**Below is text from pages 2/3 of the CDC's March 1, 2021 response (#21-00464-FOIA), with live links** (the links in the previous page are "dead" because in order to redact the submitter's identity we used an image of the original pdf and added text boxes to cover the name/email).

SARS-CoV-2 is the virus that causes coronavirus disease 2019 (COVID-19). Active infection with SARSCoV-2 is detected by [diagnostic tests](#). Currently there are two types of diagnostic tests – molecular tests that detect the virus's genetic material and antigen tests that detect specific proteins on the surface of the virus. For current data showing the total number of SARS-CoV-2-positive cases and deaths, visit the [CDC COVID-19 Data Tracker](#), which shows cases and deaths in the United States broken down by state and county, daily trends in the number of cases by state, and other parameters.

Evidence of SARS-CoV-2 infection can be found in a study entitled, [Pathology and Pathogenesis of SARSCoV-2 Associated with Fatal Coronavirus Disease](#), which includes electron microscopy images of SARSCoV-2 in infected lung and upper airway tissues as well as staining of lung and upper airway tissues using an antibody against SARS-CoV-2. The specimens analyzed in this study were from patients with common signs and symptoms associated with COVID-19, including fever, cough, and shortness of breath. All patients had abnormal findings on chest radiographs. There are other similar studies publicly available online. To aid in locating other related studies, please see the articles suggested in the "Similar Articles" and "Cited by" section on the manuscript's [PubMed entry](#).

The SARS-CoV-2 virus may be isolated from human clinical specimens by culturing in cells. In January 2020, CDC [isolated the SARS-CoV-2 virus](#) from a clinical specimen from the first confirmed case of COVID-19 in the United States. There are other similar studies published describing the isolation and characterization of SARS-CoV-2 from human clinical specimens. To aid in locating other related studies, please see the articles suggested in the "Similar Articles" and "Cited by" section on the manuscript's [PubMed entry](#). There are also [several publications](#) documenting SARS-CoV-2 infection and transmission among presymptomatic and asymptomatic individuals.

For information about the SARS-CoV-2 genome sequence, see the NIH GenBank website (<https://www.ncbi.nlm.nih.gov/genbank/sars-cov-2-seqs/>), which includes over 44,000 sequences as of December 7, 2020.



## FOIA: re Purification of SARS-COV-2

Tue, Mar 2, 2021 at 9:50 AM

To: foiarequests@cdc.gov

Dear Freedom of Information Officer,

This is a formal request for access to general records, made under the *Freedom of Information Act*.

### Description of Requested Records:

All studies and/or reports in the possession, custody or control of the Centers for Disease Control and Prevention (CDC) and/or the Agency for Toxic Substances and Disease Registry (ATSDR) describing the **purification** of "SARS-COV-2" said to have caused disease in humans (via maceration, filtration and use of an ultracentrifuge; also referred to at times by some people as "isolation"), directly from a sample taken from a diseased human, where the patient sample was not first combined with any other source of **genetic** material (i.e. monkey kidney cells aka Vero cells; fetal bovine serum).

Please note that I am not requesting studies/reports where researchers failed to **purify** the suspected "virus" and instead:

- cultured an unpurified sample or other unpurified substance, and/or
- performed an amplification test (i.e. a PCR test) on all the RNA from a patient sample or from a cell culture, or on genetic material from any unpurified substance, and/or
- sequenced the total RNA from a patient sample or from a cell culture or from any unpurified substance, and/or
- produced electron microscopy images of unpurified things.

For further clarity, please note I am already aware that according to virus theory a "virus" requires host cells in order to replicate, and I am **not** requesting records describing the **replication** of a "virus" without host cells.

Further, I am **not** requesting records that describe a suspected "virus" floating in a vacuum; I am simply requesting records that describe its **purification** (**separation** from everything else in the patient sample, as per standard laboratory practices for the purification of other small things).

Please also note that my request is **not limited** to records that were authored by the CDC or ATSDR or that pertain to work done at/by the CDC or ATSDR. Rather, my request includes any record matching the above description, for example (but not limited to) any published peer-reviewed study authored by anyone, anywhere, ever that has been downloaded or printed by the CDC or ATSDR and possibly (but not necessarily) relied on as evidence of a disease-causing "virus".

If any records match the above description of requested records and are currently available to the public elsewhere, please provide enough information about each record so that I may identify and access each one with certainty (i.e. title, author(s), date, journal, where the public may access it). Please provide URLs where possible.

### Format:

Pdf documents sent to me via email; I do not wish for anything to be shipped to me.

### Complexity

Please Note, this is not a complex request nor is it a request that will generate too many records to search through. I have already done a preliminary record search through Google Scholar and have read many scientific papers on this subject. I have not found any responsive publicly available scientific records including records referenced and published by the USA CDC. The alleged SARS-COV-2 virus is the critical focus of the CDC so CDC scientists should have this information if it exists readily available. I already have a response (#20-02166-FOIA) from the CDC from November where no records were found, so only need an update since then. So the timeframe for this request should be the standard 30 days. I am happy to discuss further if you believe otherwise.

Kind Regards



Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30333

March 3, 2021

[REDACTED]

[REDACTED]

This letter is our final response to your attached Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of March 1, 2021, assigned #21-00795-FOIA.

For administrative convenience and to fully respond to your request, program staff have provided the following information below with corresponding web links.

SARS-CoV-2 is the virus that causes coronavirus disease 2019 (COVID-19). Active infection with SARS-CoV-2 is detected by [diagnostic tests](#). Currently there are two types of diagnostic tests – molecular tests that detect the virus's genetic material and antigen tests that detect specific proteins on the surface of the virus. For current data showing the total number of SARS-CoV-2-positive cases and deaths, visit the [CDC COVID-19 Data Tracker](#), which shows cases and deaths in the United States broken down by state and county, daily trends in the number of cases by state, and other parameters.

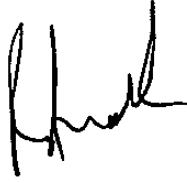
Evidence of SARS-CoV-2 infection can be found in a study entitled, [Pathology and Pathogenesis of SARS-CoV-2 Associated with Fatal Coronavirus Disease](#), which includes electron microscopy images of SARS-CoV-2 in infected lung and upper airway tissues as well as staining of lung and upper airway tissues using an antibody against SARS-CoV-2. The specimens analyzed in this study were from patients with common signs and symptoms associated with COVID-19, including fever, cough, and shortness of breath. All patients had abnormal findings on chest radiographs. There are other similar studies publicly available online. To aid in locating other related studies, please see the articles suggested in the "Similar Articles" and "Cited by" section on the manuscript's [PubMed entry](#).

The SARS-CoV-2 virus may be isolated from human clinical specimens by culturing in cells. In January 2020, CDC [isolated the SARS-CoV-2 virus](#) from a clinical specimen from the first confirmed case of COVID-19 in the United States. There are other similar studies published describing the isolation and characterization of SARS-CoV-2 from human clinical specimens. To aid in locating other related studies, please see the articles suggested in the "Similar Articles" and "Cited by" section on the manuscript's [PubMed entry](#). There are also [several publications](#) documenting SARS-CoV-2 infection and transmission among pre-symptomatic and asymptomatic individuals.

For information about the SARS-CoV-2 genome sequence, see the NIH GenBank website (<https://www.ncbi.nlm.nih.gov/genbank/sars-cov-2-seqs/>), which includes over 44,000 sequences as of December 7, 2020.

If you need any further assistance or would like to discuss any aspect of the records provided please contact either our FOIA Requester Service Center at 770-488-6399 or our FOIA Public Liaison at 770-488-6277.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Andoh', with a stylized, cursive script.

Roger Andoh  
CDC/ATSDR FOIA Officer  
Office of the Chief Operating Officer  
(770) 488-6399  
Fax: (404) 235-1852

21-00795-FOIA



**Below is the text of the CDC's March 3, 2021 response, with live links** (the links in the previous page are "dead" because in order to redact the submitter's identity we used an image of the original pdf and added text boxes to cover the name/email).

**Via email:** [REDACTED]

Dear [REDACTED]:

This letter is our final response to your attached Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of March 1, 2021, assigned #21-00795-FOIA.

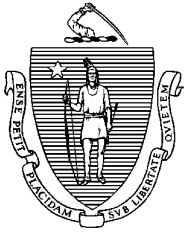
For administrative convenience and to fully respond to your request, program staff have provided the following information below with corresponding web links.

SARS-CoV-2 is the virus that causes coronavirus disease 2019 (COVID-19). Active infection with SARSCoV-2 is detected by [diagnostic tests](#). Currently there are two types of diagnostic tests – molecular tests that detect the virus's genetic material and antigen tests that detect specific proteins on the surface of the virus. For current data showing the total number of SARS-CoV-2-positive cases and deaths, visit the [CDC COVID-19 Data Tracker](#), which shows cases and deaths in the United States broken down by state and county, daily trends in the number of cases by state, and other parameters.

Evidence of SARS-CoV-2 infection can be found in a study entitled, [Pathology and Pathogenesis of SARSCoV-2 Associated with Fatal Coronavirus Disease](#), which includes electron microscopy images of SARSCoV-2 in infected lung and upper airway tissues as well as staining of lung and upper airway tissues using an antibody against SARS-CoV-2. The specimens analyzed in this study were from patients with common signs and symptoms associated with COVID-19, including fever, cough, and shortness of breath. All patients had abnormal findings on chest radiographs. There are other similar studies publicly available online. To aid in locating other related studies, please see the articles suggested in the "Similar Articles" and "Cited by" section on the manuscript's [PubMed entry](#).

The SARS-CoV-2 virus may be isolated from human clinical specimens by culturing in cells. In January 2020, CDC [isolated the SARS-CoV-2 virus](#) from a clinical specimen from the first confirmed case of COVID-19 in the United States. There are other similar studies published describing the isolation and characterization of SARS-CoV-2 from human clinical specimens. To aid in locating other related studies, please see the articles suggested in the "Similar Articles" and "Cited by" section on the manuscript's [PubMed entry](#). There are also [several publications](#) documenting SARS-CoV-2 infection and transmission among presymptomatic and asymptomatic individuals.

For information about the SARS-CoV-2 genome sequence, see the NIH GenBank website (<https://www.ncbi.nlm.nih.gov/genbank/sars-cov-2-seqs/>), which includes over 44,000 sequences as of December 7, 2020.



The Commonwealth of Massachusetts  
Executive Office of Health and Human Services  
Department of Public Health  
Bureau of Infectious Disease and Laboratory Sciences  
305 South Street, Jamaica Plain, MA 02130

CHARLES D. BAKER  
Governor

KARYN E. POLITO  
Lieutenant Governor

Office of Integrated Surveillance and Informatics Services  
Tel: (617) 983-6801  
Fax: (617) 983-6813

MARYLOU SUDDERS  
Secretary

MARGRET R. COOKE  
Acting Commissioner

Tel: 617-624-6000  
[www.mass.gov/dph](http://www.mass.gov/dph)

August 25, 2021

Via email to: [117383-57122200@requests.muckrock.com](mailto:117383-57122200@requests.muckrock.com)

Ramola Dharmaraj  
MuckRock News  
DEPT MR 117383  
411A Highland Ave  
Somerville, MA 02144-2516

**Re: Public Record Request BIDLS-2021-140**

Dear Ramola Dharmaraj:

This letter is in regard to the above referenced public record request received by the Massachusetts Department of Public Health (the "Department" or "DPH") on August 10, 2021. This request has been assigned a tracking number: **BIDLS-2021-140**. Specifically, you requested:

Request for all Scientific White Papers, Reports, Studies Related to

- 1) the Isolation of SARS-COV-2 Virus/COVID-19 Virus in human beings and
- 2) the Isolation of SARS-COV-2 Virus/COVID-19 Virus, "Delta Variant" in human beings  
directly from a sample taken from a labeled COVID-Diseased or COVID-Dead Patient (diseased or dead only due to SARS-COV-2 Virus/COVID-19 Virus or Delta Variant of SARS-COV-2 Virus/COVID-19 Virus), where the sample was not first combined in any way with any other genetic material, and where the Patient did not have any other disease such as Pneumonia, Influenza, etc;
- 3) the Inducement of the COVID-19 disease in a healthy person using this Isolate of the SARS-COV-2 Virus/COVID-19 Virus proving Koch's postulates of Disease Transmission;
- 4) the Inducement of the COVID-19 disease in a healthy person using this Isolate of the

“Delta Variant” of the SARS-COV-2 Virus/COVID-19 Virus proving Koch's postulates of Disease Transmission;

and forming the basis for all ill-advised restrictions and advisories--particularly regarding public transport, masking and vaccines in schools and colleges--previously made, being made, or planned by the Massachusetts Department of Public Health, the Massachusetts Governor, the CDC, and the US Dept of Health and Human Services citing the Existence of a Virus, a Variant, a Pandemic, and a Public Health Emergency.

Clarification 1: This is a request for full disclosure of all scientific studies, reports, and white papers related to the isolation of the SARS-COV-2/COVID-19 virus and Delta Variant in human beings, which form the Proof of Virus, Proof of Pandemic, and Reason for Use/Basis used for all the questionable “Public Health” “mandates” “guidances” “advisories” and “requirements” issuing forth from the Massachusetts Dept of Public Health, the Governor's office, and the CDC, for wearing hazardous health-destroying masks, feudally directing human behavior in distancing six feet, and coercing the taking of an experimental and deadly mRNA vaccine (Which has now been recorded, as of August 3, 2021 by the CDC, EudraVigilance, MHRA Yellow Card Scheme and other Vaccine Adverse Reactions Databases to have now jointly caused 35,227 DEATHS and 3,679,601 INJURIES ( as reported to CDC VAERS (USA) through to July 23, 2021, to EudraVigilance (which covers 27 countries only in the EU reporting to the EU EMA EudraVigilance) through to July 31, 2021, and to the Yellow Card System (U.K.) through to July 21, 2021.”--Sources:

CDC: 11,940 DEAD 618,648 Injuries and 1,175 Unborn Babies DEAD Following COVID-19 Shots/Health Impact News, August 1, 2021;

20,595 DEAD 1.9 Million Injured (50% SERIOUS) Reported in European Union's Database of Adverse Drug Reactions for COVID-19 Shots/Health Impact News, August 3, 2021)

Clarification 2: Isolate means “to separate something from other things with which it is connected or mixed”--Cambridge Dictionary definition.

Clarification 3: This request is not for information on something procured by means of

- 1) Culturing something,
- 2) Nasally swabbing something from any randomly sick (with some other disease) or healthy person,
- 3) Amplifying something via PCR Test (Which its inventor Dr. Kary Mullis has clearly stated is not to be used to diagnose any disease),
- 4) the Sequencing of something,
- 5) or the Computer-Generated Sequencing of something.

The Department has no responsive records to your request.



DPH now considers this public records request closed. If you wish to challenge this response, and your request was received in writing, you may appeal to the Supervisor of Records following the procedure set forth in 950 CMR 32.08, a copy of which is attached. Pursuant to G.L. c. 66, §10A, you may also seek judicial review by commencing a civil action in Suffolk Superior Court.

Please contact Ann Scales, Director of Media Relations at 617-624-5253 with any questions. In any communication regarding this request, please reference the assigned tracking number: **BIDLS-2021-140**.

Sincerely,  
Gillian Haney, MPH  
Director of Office of Integrated Surveillance and Informatics Services (ISIS)  
Bureau of Infectious Disease and Laboratory Sciences, Massachusetts Department of Public Health

CC: Helen Rush-Lloyd  
Records Access Officer

Ann Scales  
Director of Media Relations

Code of Massachusetts Regulations  
Title 950: Office of the Secretary of the Commonwealth  
Chapter 32.00: Public Records Access (Refs & Annos)

**Effective 1/1/17**

950 CMR 32.08  
32.08: Appeals

32.08: Appeals

(1) Appeals to the Supervisor.

- (a) 950 CMR 32.08 shall not apply to records in which an individual, or a representative of the individual, has a unique right of access to the records through statutory, regulatory, judicial or other applicable means.
- (b) a requester may petition the Supervisor for failure by a records access officer to comply with a requirement of 950 CMR 32.00.
- (c) an oral request, while valid as a public record request, shall not be the basis of an appeal under 950 CMR 32.08.
- (d) petitions for appeal of a response by a records access officer must be made within 90 calendar days of the date of the response by a records access officer.
- (e) petitions for appeal of a failure to respond within the timeliness requirements of 950 CMR 32.00 must be made within 90 calendar days of the request.
- (f) all petitions for appeal shall be in writing and shall specifically describe the nature of the requester's objections to the response or failure to timely respond.
- (g) requesters shall provide to the Supervisor complete copies of all correspondence associated with the petition, including:
  1. a complete copy of the letter by which the request was made, including in the case of electronic communications all header information indicating time, date, subject, sender and recipient email addresses; and
  2. a complete copy of all written responses associated with requests subject to the petition for appeal, including in the case of electronic communications all header information indicating time, date, subject, sender and recipient email addresses.
- (h) in petitioning the Supervisor, the requester shall provide a copy of such petition to the records access officer associated with such petition.
- (i) if the requester's petition for appeal is related to a previous appeal to the Supervisor, the requester's petition shall refer to the previous appeal number.
- (j) petitions under 950 CMR 32.08 received before 4:00 P.M. shall be opened on the day of receipt. Petitions received after 4:00 P.M. shall be opened on the following business day.

(2) Dispositions of Appeals

- (a) the supervisor shall issue a written determination regarding any petition submitted in accordance with 950 CMR 32.08(1) not later than ten business days following receipt of the petition.
- (b) the Supervisor may deny an appeal for, among other reasons if, in the opinion of the Supervisor:
  1. the public records in question are the subjects of disputes in active litigation, administrative hearings or mediation;
  2. the request is designed or intended to harass, intimidate, or assist in the commission of a crime;
  3. the public records request is made solely for a commercial purpose;
  4. the requester has failed to comply with the provisions of 950 CMR 32.08(2).

32.08: continued

- (c) upon a determination by the Supervisor that a violation has occurred, the Supervisor shall order timely and appropriate relief.
- (3) Hearings and Conferences.
  - (a) the Supervisor may conduct a hearing pursuant to the provisions of 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedure*. The decision to hold a hearing shall be solely in the discretion of the Supervisor.
    - 1. said rules shall govern the conduct and procedure of all hearings conducted pursuant to 950 CMR 32.08.
    - 2. nothing in 950 CMR 32.08 shall limit the Supervisor from employing any administrative means available to resolve summarily any appeal arising under 950 CMR 32.00.
  - (b) the Supervisor may order conferences for the purpose of clarifying and simplifying issues and otherwise facilitating or expediting the investigation or proceeding. The decision to hold a conference shall be solely in the discretion of the Supervisor.
- (4) In Camera Inspections and Submissions of Data.
  - (a) the Supervisor may require an inspection of the requested record(s) in camera during any investigation or any proceeding initiated pursuant to 950 CMR 32.08.
  - (b) the Supervisor may require the records access officer to produce other records and information necessary to reach a determination pursuant to 950 CMR 32.08.
  - (c) the Supervisor does not maintain custody of documents received from a records access officer submitted for an in camera review. The documents submitted for an in camera review do not fall within the definition of public records. M.G.L. c. 4, §7(26).
  - (d) upon a determination of the public record status of the documents, they are promptly returned to the custodian, and no copies shall be retained by the Supervisor.
  - (e) any public record request made to the Division for records being reviewed in camera would necessarily be denied, as the office would not be the custodian of those records.
  - (f) attorney-client privileged records voluntarily submitted to Supervisor:
    - 1. a records access officer may voluntarily submit documents to the Supervisor for in camera review;
    - 2. such submission shall not waive any legally applicable privileges claimed by the agency or municipality.
- (5) Custodial Indexing of Records
  - (a) the Supervisor may require a records access officer or custodian to compile an index of the requested records within the context of a public records appeal number under 950 CMR 32.08.
  - (b) said index shall be a public record and shall meet the following requirements:
    - 1. the index shall be contained in one document, complete in itself;
    - 2. the index shall adequately describe each withheld record or redaction from a released record;
    - 3. the index must state the exemption or exemptions claimed for each withheld record or each redaction of a record; and
    - 4. the descriptions of the withheld material and the exemption or exemptions claimed for the withheld must be sufficiently specific to permit the Supervisor to make a reasoned judgment as to whether the material is exempt.
  - (c) nothing in 950 CMR 32.08 shall preclude the Supervisor from employing alternative or supplemental procedures to meet the particular circumstances of each appeal.



THE COMMONWEALTH OF MASSACHUSETTS  
OFFICE OF THE GOVERNOR

STATE HOUSE • ROOM 271  
BOSTON, MASSACHUSETTS 02133  
TEL: (617) 725-4030 • FAX: (617) 727-8290

GOVERNOR'S LEGAL OFFICE

CHARLES D. BAKER  
GOVERNOR

KARYN E. POLITO  
LIEUTENANT GOVERNOR

ROBERT C. ROSS  
CHIEF LEGAL COUNSEL

MICHAEL A. KANEB  
DEPUTY CHIEF LEGAL COUNSEL

ELIZABETH F. DENNISTON  
DEPUTY LEGAL COUNSEL

KIRK G. HANSON  
DEPUTY LEGAL COUNSEL

NICK D. BRANDT  
DEPUTY LEGAL COUNSEL

LAUREN GREENE-PETRIGNO  
DEPUTY LEGAL COUNSEL

August 11, 2021

Ramola Dharmaraj

VIA E-mail: [117382-80619351@requests.muckrock.com](mailto:117382-80619351@requests.muckrock.com)

Dear Ms. Dharmaraj:

I write in response to your request to the Office of the Governor, dated August 7, 2021, seeking "All Scientific White Papers, Reports, Studies Related to

- 1) the Isolation of SARS-COV-2 Virus/COVID-19 Virus in human beings and
- 2) the Isolation of SARS-COV-2 Virus/COVID-19 Virus, "Delta Variant" in human beings directly from a sample taken from a labeled COVID-Diseased or COVID-Dead Patient (diseased or dead only due to SARS-COV-2 Virus/COVID-19 Virus or Delta Variant of SARS-COV-2 Virus/COVID-19 Virus), where the sample was not first combined in any way with any other genetic material, and where the Patient did not have any other disease such as Pneumonia, Influenza, etc;
- 3) the Inducement of the COVID-19 disease in a healthy person using this Isolate of the SARS-COV-2 Virus/COVID-19 Virus proving Koch's postulates of Disease Transmission;
- 4) the Inducement of the COVID-19 disease in a healthy person using this Isolate of the "Delta Variant" of the SARS-COV-2 Virus/COVID-19 Virus proving Koch's postulates of Disease Transmission; and forming the basis for all ill-advised restrictions and advisories--particularly regarding public transport, masking and vaccines in schools and colleges..."<sup>1</sup>

We have received your correspondence and have concluded that we have no records that fall within the scope of your request. We suggest that you inquire to the Massachusetts Department of Public Health for further help with your request. I have listed the information for their Records Access Officer below. Thank you.

---

<sup>1</sup> Please note that the Office of the Governor is not one of the instrumentalities enumerated in G.L. c. 4, §7, cl. 26, and therefore its records are not subject to disclosure under the public records law. The Supreme Judicial Court has so held. See Lambert v. Executive Director of the Judicial Nominating Council, 425 Mass. 406, 409 (1997). Notwithstanding Lambert, it is the voluntary practice of the Office to consider and to respond to public records requests on a case-by-case basis.



DPH (RAO): Helen Rush-Lloyd  
[DPH.RAO@state.ma.us](mailto:DPH.RAO@state.ma.us)  
(617) 624-5223

Sincerely,

Paige Ferreira  
Legal Assistant / Records Access Officer

---

## FOIA request

---

Beatrice Scova <[REDACTED]>  
To: "christinem@fluoridefreepeel.ca" <christinem@fluoridefreepeel.ca>

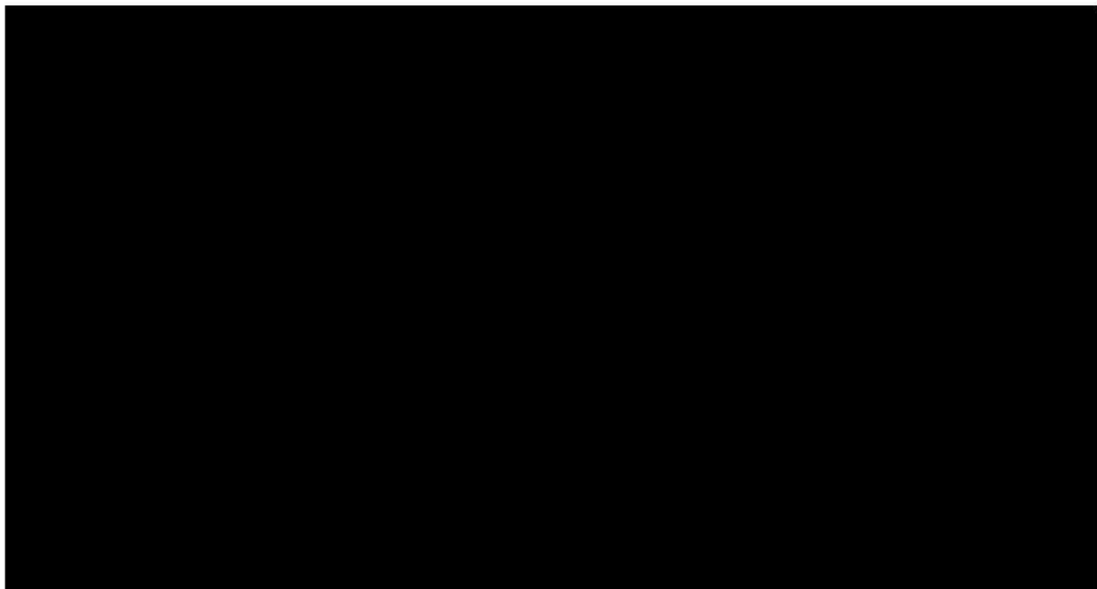
Sun, Sep 5, 2021 at 11:12 AM

Dear Christine

We hope you are well, and in good spirit.

This is a copy of the request we have made to the health authorities in Florida regarding purification of SARS-COV-2.  
We waited 30 days and have resent requested information.

We would like to know if there is also something else we should be doing to get this information,



God Bless

Beatrice

PS  
[REDACTED]

Subject: **Access to Info Request: records re PURIFICATION OF "SARS-COV-2"**

**August 5, 2021**

To:  
[COVID-19@flhealth.gov](mailto:COVID-19@flhealth.gov) / [1-866-779-6121](tel:1-866-779-6121).

Public Records Coordinator

4052 Bald Cypress Way-Bin A02  
Tallahassee, Florida 32399-1702  
Telephone (850) 245-4005  
FAX (850) 413-8743  
[PublicRecordsRequest@flhealth.gov](mailto:PublicRecordsRequest@flhealth.gov)

Florida Health:  
850-245-4444  
[health@flhealth.gov](mailto:health@flhealth.gov)

Department of Health (DOH)  
Kendra Washington  
Public Records Manager  
850-245- 4005  
[PublicRecordsRequest@flhealth.gov](mailto:PublicRecordsRequest@flhealth.gov)

Department of Agriculture & Consumer Services (DACS)  
Steven Hall, General Council & Custodian of Records  
850- 245-1000

Florida Department of Health Immunization Section  
[4052 Bald Cypress Way](#)  
Bin A11 Tallahassee, FL 32399-1719  
Phone: 1-877-888-7468 Fax: 850-922-4195  
[Immunization@FLHealth.gov](mailto:Immunization@FLHealth.gov)

Citrus County Health Department  
[3700 West Sovereign Path](#)  
[Lecanto FL 34461](#)  
352-527-0068  
[webmaster09@flhealth.gov](mailto:webmaster09@flhealth.gov)

**Dear Public Records Coordinators, Managers, Custodians,**

This is a formal request for access to general records, made under **Freedom of Information Act**.

**Description of Requested Records:**

All studies and/or reports in the possession, custody or control of the Florida Health Authorities, describing the **purification** of any “**COVID-19 virus**” (aka “SARS-COV-2”, including any alleged “variants” i.e. “B.1.1.7”, “B.1.351”, “P.1”) directly from a sample taken from a diseased human, where the patient sample was not first combined with any other source of **genetic** material (i.e. monkey kidney cells aka Vero cells; fetal bovine serum).

Please note that I am not requesting studies/reports where researchers failed to **purify** the suspected “virus” (separate the alleged “virus” from everything thing else in the patient sample) and instead:

- cultured an unpurified sample or other unpurified substance, and/or
- performed an amplification test (i.e. a PCR test) on the total RNA from a patient sample or from a cell culture, or on genetic material from any unpurified substance, and/or
- fabricated a genome based on PCR-detected sequences in the total RNA from a patient sample or from a cell culture or from any unpurified substance, and/or
- produced electron microscopy images of unpurified things in a cell culture.

**Clarification of Request**

For further clarity, please note I am already aware that according to virus theory a “virus” requires host cells in order to replicate, and I am **not** requesting records describing the **replication** of a “virus” without host cells.

Further, I am **not** requesting records that describe a suspected “virus” floating in a vacuum; I am simply requesting records that describe its **purification (separation)** from everything else in the patient sample, as per standard laboratory practices for the purification of other very small things).

Please note that my request includes any study/report matching the above description, for example (but not limited to) any published peer-reviewed study **authored by anyone, anywhere.**

Please also note that despite the fact that purification is an essential <https://www.torstenengelbrecht.com/en/home/> (but not sufficient) step in proving the existence of a disease-causing “virus”, as of today 90 health/science institutions globally all failed to cite even 1 record of “SARS-COV-2” purification, by anyone, anywhere, ever, <https://www.fluoridefreepeel.ca/68-health-science-institutions-globally-all-failed-to-cite-even-1-record-of-sars-cov-2-purification-by-anyone-anywhere-ever/> (including the U.S. CDC, Public Health Agency of Canada, Australian Department of Health, New Zealand Ministry of Health, European Centre for Disease Prevention and Control, UK Department for Health and Social Care, Indian Council of Medical Research, United States of America Agency for Toxic Substances and Disease Registry, National Institute of Allergy and Infectious Diseases – NIAID, Oregon Health Authority, United Kingdom Prime Minister’s Office, etc.) have all failed to provide or cite any such records, therefore to my knowledge no such records exist and if they do exist I cannot access them until I am provided a citation or URL.

Therefore in the interest of transparency and in accordance with the purposes of the legislation, if any records match the above description of requested records and are currently available to the public elsewhere, please provide enough information about each record so that I may identify and access each one with certainty (i.e. title, author(s), date, journal, where the public may access it). Please provide URLs where possible.

**Format:**

pdf documents sent to me via email; I do not wish for anything to be shipped to me.

**Contact Information:**

Thanks you in advance and best wishes,

Beatrice Biddle

---

**Fw: Public Records Request :: P071693-080621**

---

Beatrice Scova <[REDACTED]>  
To: Christine Massey <cmssyc@gmail.com>

Wed, Sep 22, 2021 at 3:58 PM

----- Forwarded Message -----

**From:** Florida Department of Health <fdh@mycusthelp.net>  
**To:** [REDACTED]  
**Sent:** Monday, September 20, 2021, 01:20:34 PM EDT  
**Subject:** Public Records Request :: P071693-080621

**Attachments:**

Thermo\_Fisher\_TaqPath\_COVID-19\_Combo\_Kit\_-\_BPHL\_SOP2.docm  
KingFisher\_TaqPath\_COVID-19\_Combo\_Kit\_SOP\_\_Revision\_J.0..pdf

--- Please respond above this line ---

Good afternoon,

Please see attached responsive records.

Regards,

**Public Records Section**

Florida Department of Health  
Office of the General Counsel  
4052 Bald Cypress Way, Bin A-02  
Tallahassee, FL 32399  
Telephone: 850-245-4005  
Fax: 850-245-4790

Email: [publicrecordsrequest@flhealth.gov](mailto:publicrecordsrequest@flhealth.gov)



---

**Fw: Public Records Request :: P073269-100421**

---

Beatrice Scova <[REDACTED]>  
To: Christine Massey <cmssyc@gmail.com>

Tue, Oct 19, 2021 at 12:08 AM

Dear Christine



Chronological order of events, and correspondences in reference to my request for documentation, and proof of isolated, purified alleged CoV-19 virus.

8/4/021 Sent by email a formal request

Florida Health responded by redirecting me to [covid-19@flhealth.gov](mailto:covid-19@flhealth.gov)

We forwarded our request to [covid-19@flhealth.gov](mailto:covid-19@flhealth.gov) and they responded due to high volume they would be delayed with a response.

Immunization Florida Health responded by saying due to high volume their response would be delayed.

8/5/2021

We registered online with the public Records Department, Florida Health, and submitted our request.

8/6/2021

Florida Department thanked us for registering online, directing us to records request, and when prompted TO CONFIRM, all we got was PAGE NOT FOUND.

A reference # was assigned to us, P071693-080621.

8/7/2021

Florida Health sent a password confirmation, yet the link DID NOT WORK. ERROR page would pop up.

After about a month with no responses other than what is above, we reached out to the Citrus County Health Department by phone and email.

In the Citrus County Health Department, we spoke with Jackie Shaw, who advised us to speak with Freeda Dunn from immunization. We then spoke with Kim Jackson who told us to speak with Anna Murphy from Human Relations. We

are being sent in circles. Then we were directed to Denise Popper who told us to speak to the Supervisor Kim Jackson... (Why are we speaking to Human Relations, when Miss Kim Jackson is the supervisor of the Department?). After speaking with all of these women, with no directions and answers we were told to speak with Audry Stasko, Public Info Officer, who told us the County cannot give us any information until they hear from Florida public Health. Imagine paying all these people in that office for that...

We then called Kendra Washington Public Records Manager, Department of Health, who said she was closing P072535 from (8/6/21), as it was an old reference number and duplicate of the second request we made. She said to use reference # P071693 from now on.

9/5/2021

We sent a second FOIA request to

Florida health ([health@flhealth.gov](mailto:health@flhealth.gov))

[PublicRecordsRequest@flhealth.gov](mailto:PublicRecordsRequest@flhealth.gov) 850-245-4005 Kendra Washington

Citrus County Health Department [webmaster09@flhealth.gov](mailto:webmaster09@flhealth.gov)

[Immunization@flhealth.gov](mailto:Immunization@flhealth.gov)

Department of Agriculture and Consumer Services DACS Steven Hall General Council and Custodian of Records

Florida immunization responded due to high volume your request may be delayed

[Covid-19@flhealth.gov](mailto:Covid-19@flhealth.gov) responded the same as Florida Immunization, due to high volumes your response may be delayed

9/7/2021

Florida Health online confirmed request with reference # P072535-090721. Status (Duplicate).

9/20/2021

Florida Health online sent two documents in reference to P076193-080621:

**Good afternoon,**

**Please see attached responsive records.**

**Attachments:**

[Thermo Fisher TaqPath COVID-19 Combo Kit - BPHL SOP2.docm](#)  
[KingFisher TaqPath COVID-19 Combo Kit SOP Revision J.0..pdf](#)

Regards,

**Public Records Section**

Florida Department of Health  
Office of the General Counsel  
4052 Bald Cypress Way, Bin A-02  
Tallahassee, FL 32399  
Telephone: 850-245-4005  
Fax: 850-245-4790

Email: [publicrecordsrequest@flhealth.gov](mailto:publicrecordsrequest@flhealth.gov)

9/22/2021

I wrote back:

Good afternoon,

Please be advised I'm requesting your response be provided in a formal, dated, and signed letter with a reference or file #. I've examined these records you cited, and they DO NOT describe purification of the alleged virus. They are NOT responsive to my request, so I require a corrected response.

Thank you

I noticed online they had closed my case although they had not answered my response, which their email to my told me to respond above the line.

There were over 175 pages in the documents they sent me on 9/20/2021, and I did respond on 9/22/21, as above.

None of the documents forwarded to me answered my question.

I called Miss Kendra Washington, 850-245-4005, from the Public Records Department at Florida Health and asked why my case was closed, as she didn't even look at my response. She told me she was NOT REQUIRED to give me the information I requested on the 22<sup>nd</sup> of September. I asked her to repeat this to make sure I was hearing this correctly, and she did she said NO. NO. NO, I don't have to... I then asked to speak to a supervisor. Miss Kendra Washington directed me to Torezze Porter, from the General Council Department, Florida Health public Records, 850-245-4026.

I explained to Mr. Porter the situation, we wanted to know why the case was closed when my response wasn't answered. he told me to re-submit my request, with more detail, and tell them that the documents that were provided to me did NOT respond to my request, and a new case would be re assigned to me.

As per Mr. Porters advice I resubmitted my request for the information I needed, letting them know that the documents they provided to me were NOT responsive, and I require a corrected response, and opening a new request, as deemed by law they are obligated to provide me with the proper documents.

10/7/2021

Florida Department of Health wrote back:

**Subject:** Public Records Request: P073269-100421

**Body:**

Good morning,

This is a duplicate request of P071693-080621. Responsive records were provided for that request. This matter (P073269-100421) will be closed as a duplicate.

Regards,

**Public Records Section**

Florida Department of Health  
Office of the General Counsel  
4052 Bald Cypress Way, Bin A-02  
Tallahassee, FL 32399  
Telephone: 850-245-4005  
Fax: 850-245-4790

Email: [publicrecordsrequest@flhealth.gov](mailto:publicrecordsrequest@flhealth.gov)

I called Torezze Porter as well as emailed him twice since then, and he still has NOT responded, as more and more people are being subjected to these deadly JABS.

September 24, 2021

Attn: Tonya Y. Hatten, Records Custodian  
Metro Public Health Department  
2500 Charlotte Avenue  
Nashville, TN 37209

Dear Tonya Hatten:

Please provide all records in the possession, custody, and/or control of the Metro Public Health Department describing the isolation of a SARS-COV-2 virus, directly from a sample taken from a diseased patient, where the patient's sample was not first combined with any other source of genetic material (i.e. monkey kidney cells aka vero cells; liver cancer cells, etc.).

Please note that I am using "isolation" in the everyday sense of the word: the act of separating a thing(s) from everything else. I am not referring to the "isolation of SAR-COV-2" as it relates to:

- the culturing of something,
- the performance of an amplification test (i.e. a [RT-]PCR test), or
- the sequencing of something.

Please provide all records in the possession, custody, and/or control of the Metro Public Health Department describing the complete matching genomic sequences of the SARS-COV-2 virus sample isolated from a diseased patient in Metro Nashville, Tennessee, with the SARS-COV-2 virus sample isolated from "patient zero" in Wuhan, China.

Please also note that my request is not limited to records that were authored by the Metro Public Health Department or that pertain to work done by the Metro Public Health Department. My request includes any sort of record, for example (but not limited to) any published peer-reviewed study that the Metro Public Health Department has downloaded or printed. If any records match the above description of requested records and are currently available to the public elsewhere, please provide enough information about each record so that I may identify and access each record with certainty (i.e. title, author(s), date, journal name, where the public may access it).

Please provide the records of studies (i.e. title, author(s), date, journal name, where the public may access it) that indisputably show that SAR-COV-2 virus has been proven to exist (complete purification, isolation, and definition of biochemical properties plus electron micrograph).

Please provide the records of studies (i.e. title, author(s), date, journal name, where the public may access it) that indisputably show that the aforementioned virus causes a disease called COVID-19 (and also that other factors like malnutrition, toxins, electromagnetic wave interference, etc. do not at least co-determine the course of disease). Please note that electromagnetic wave interference, industrial poisons, various drugs, and/or other non-germ factors (such as antipsychotics, opioid analgesics, anticholinergics, and/or antidepressants) may be a cause of respiratory diseases, such as pneumonia and thus also COVID-19.

Please provide the records of at least two studies (i.e. title, author(s), date, journal name, where the public may access it) that indisputably show that vaccinations are completely safe and effective.

## **Delivery preference**

Electronic



## Proof of Isolation of the SAR-COV-2 virus Resources

I am enclosing the various resources that aided me in creating the records requests:

<https://rxisk.org/medications-compromising-covid-infections/>

RxISK: In the Midst of the SARS-COV-2 Pandemia, Caution is Needed With Commonly Used Drugs That Increase the Risk of Pneumonia

By Joan-Ramon Laporte, M.D. and David Healy MD FRCPsych

<https://andrewkaufmanmd.com/sovi/>

Statement On Virus Isolation (SOVI)

by Morell, Cowan & Kaufman

<https://www.whatdotheyknow.com/request/679566/response/1625332/attach/html/2/872%20FOI%20All%20records%20describing%20isolation%20of%20SARS%20COV%202.pdf.html>

WhatDoTheyKnow: Public Health England Documents held showing SARS-COV2 has been isolated and Causes COVID-19

<https://www.fluoridefreepeel.ca/fois-reveal-that-health-science-institutions-around-the-world-have-no-record-of-sars-cov-2-isolation-purification/>

Fluoride Free Peel: FOIs reveal that health/science institutions around the world have no record of SARS-COV-2 isolation/purification, anywhere, ever

<https://www.torstenengelbrecht.com/en/virus-mania/>

*Virus Mania: Corona/COVID-19, Measles, Swine Flu, Avian Flu, Cervical Cancer, SARS, BSE, Hepatitis C, AIDS, Polio, Spanish Flu: How the Medical Industry Continually Invents Epidemics, Making Billion-Dollar Profits at Our Expense*

By Torsten Engelbrecht, Claus Köhnlein, MD, Dr. Samantha Bailey, MD, and Dr. Stefano Scoglio, pages 51 and 387, ISBN# 9783752629781

I want to thank you in advance for your time and consideration.

Jrucka Embry, E.I.T.



## PUBLIC RECORD REQUEST RESPONSE FORM

Metro Public Health Department  
2500 Charlotte Avenue, Suite 115  
Nashville, TN 37209

September 29, 2021

Irucka Embry:

In response to your records request received on **September 24, 2021**, our office is taking the action(s)<sup>1</sup> indicated below:

☐ The public record(s) responsive to your request will be made available for inspection:

Location: \_\_\_\_\_

Date & Time: \_\_\_\_\_

☐ Copies of public record(s) responsive to your request are:

☐ Attached;

☐ Available for pickup at the following location:

2500 Charlotte Avenue, First Floor, Suite 115 (Medical Records); or

☐ Being delivered via: ☐ USPS First-Class Mail ☐ Electronically ☐ Other: \_\_\_\_\_.

☒ Your request is denied on the following grounds:

☐ Your request was not sufficiently detailed to enable identification of the specific requested record(s). You need to provide additional information to identify the requested record(s).

☐ Questions which seek information rather than the reproduction of record(s) does not require a response under TPRA.

☒ No such record(s) exists, or this office does not maintain record(s) responsive to your request.

☐ No proof of Tennessee citizenship was presented with your request. Your request will be reconsidered upon presentation of an adequate form of identification.

☐ You are not a Tennessee citizen.

☐ You have not paid the estimated copying/production fees.

☐ The following state, federal, or other applicable law prohibits disclosure of the requested records:  
\_\_\_\_\_.

☐ It is not practicable for the records you requested to be made promptly available for inspection and/or copying because:

- ☐ It has not yet been determined that records responsive to your request exist; or
- ☐ The office is still in the process of retrieving, reviewing, and/or redacting the requested records.

The time reasonably necessary to produce the record(s) or information and/or to make a determination of a proper response to your request due to the volume of emails located for inspection is:

\_\_\_ **weeks** given the volume of emails produced by the requested production and the resulting pages when produced by PDF. The request should be produced by \_\_\_\_\_; however, the Department may contact you if there are additional delays. The Department will produce the request by email unless another means of production is requested.

If you have any additional questions regarding your record request, please contact [Records Custodian or Public Records Request Coordinator].

Sincerely,

*Tonya W. Foreman*

Public Record Request Coordinator  
Metro Public Health Department  
2500 Charlotte Avenue, Ste. 115  
Nashville, TN 37209  
P: (615) 340-5677  
F: (615) 340-8565  
E: [MPHDPubRecRequest@nashville.gov](mailto:MPHDPubRecRequest@nashville.gov)

## Access to Info Request: PURIFICATION OF “SARS-COV-2”

This is a formal request for access to general records, made under *Freedom of Information Act*.

### Description of Requested Records:

All studies and/or reports in the possession, custody or control of the Michigan Department of Health and Human Services(MDHHS), describing the **purification** of any “**COVID-19 virus**” (aka “SARS-COV-2”, including any alleged “variants” i.e. “B.1.1.7”, “B.1.351”, “P.1”, “Delta”) directly from a sample taken from a diseased human, where the patient sample was not first combined with any other source of **genetic** material (i.e. monkey kidney cells aka Vero cells; fetal bovine serum).

Please note that I am not requesting studies/reports where researchers failed to **purify** the suspected “virus” (separate the alleged “virus” from everything thing else in the patient sample) and instead:

- cultured an unpurified sample or other unpurified substance, and/or
- performed an amplification test (i.e. a PCR test) on the total RNA from a patient sample or from a cell culture, or on genetic material from any unpurified substance, and/or
- fabricated a genome based on PCR-detected sequences in the total RNA from a patient sample or from a cell culture or from any unpurified substance, and/or
- produced electron microscopy images of unpurified things in a cell culture.

### Clarification of Request

For further clarity, please note I am already aware that according to virus theory a “virus” requires host cells in order to replicate, and I am **not** requesting records describing the **replication** of a “virus” without host cells.

Further, I am **not** requesting records that describe a suspected “virus” floating in a vacuum; I am simply requesting records that describe its **purification** (**separation** from everything else in the patient sample, as per standard laboratory practices for the purification of other very small things).

Please note that my request includes any study/report matching the above description, for example (but not limited to) any published peer-reviewed study **authored by anyone, anywhere**.

Please also note that despite the fact that [purification is an essential](#) (but not sufficient) step in proving the existence of a disease-causing “virus”, as of today [68 institutions globally](#) (including the U.S. CDC, Public Health Agency of Canada, Australian Department of Health, New Zealand Ministry of Health, European Centre for Disease Prevention and Control, UK Department for Health and Social Care, Indian Council of Medical Research)

have all failed to provide or cite any such records, therefore to my knowledge no such records exist and if they do exist I cannot access them until I am provided a citation or URL.

Therefore in the interest of transparency and in accordance with the purposes of the legislation, if any records match the above description of requested records and are currently available to the public elsewhere, please provide enough information about each record so that I may identify and access each one with certainty (i.e. title, author(s), date, journal, where the public may access it). Please provide URLs where possible. (or Pdf documents sent to me via email; I do not wish for anything to be shipped to me.)

Thank you

**Contact Information:**

Last name: Nihem

First name: Andrew

Phone: 248-210-7237

Email: arnihem@hotmail.com





---

RE: Public Records Request, Reference # H012477-080421.

Dear Mr Nihem,

This notice is issued in response to your request, legally received by the Michigan Department of Health and Human Services (Department) on August 05, 2021, requesting information under the Freedom of Information Act (FOIA), MCL 15.231 *et seq.*

Your request is denied.

**To the best of the Department's knowledge, information, and belief, this Department does not possess or maintain records under the description you provided or by other names reasonably known to the Department.**

As to the denial, the Department is obligated to inform you that under MCL 15.240 §10 the following remedies are available:

1. Appeal this decision in writing to the Legal Affairs Administration of the Department of Health and Human Services, PO Box 30195, Lansing, MI 48909. The writing must specifically state the word "appeal" and must identify the reason or reasons you believe the denial should be reversed. The Department must respond to your appeal within ten days of receipt. Under unusual circumstances, the time for response to your appeal may be extended by ten business days.
2. File an action in the appropriate court within 180 days after the date of the final determination to deny the request. If you prevail in such an action, the court is to award reasonable attorney fees, costs, disbursements, and possible damages.

The Department's FOIA policies and procedures are available at [Policies and Procedures](#).

Sincerely,

Ruth O'Connor  
Bureau of Legal Affairs

MONTGOMERY COUNTY  
BOARD OF COMMISSIONERS  
VALERIE A. ARKOOSH, MD, MPH, CHAIR  
KENNETH E. LAWRENCE, JR., VICE CHAIR  
JOSEPH C. GALE, COMMISSIONER



OFFICE OF THE SOLICITOR  
MONTGOMERY COUNTY COURTHOUSE • PO Box 311  
NORRISTOWN, PA 19404-0311  
610-278-3033  
FAX: 610-278-3069 • TDD: 610-631-1211  
WWW.MONTCOPA.ORG

August 30, 2021

VIA E-MAIL

King of Prussia,

Re: Right-to-Know Request No. OR21-553

Dear M

On August 26, 2021, the open-records officer of Montgomery County received your written request for information. The County is responding to your request under the Pennsylvania Right-To-Know Law, 65 P.S. §§ 67.101, *et seq.* (RTKL). You asked for the following:

"...I am seeking any records that describe the isolation of a "COVID-19 virus" (aka "SARS-CoV-2") from an unadulterated sample taken from a diseased human, where the patient sample was not first combined with any other source of genetic material. Isolate meaning a thing is separated from all other material surrounding it.

Note: I am NOT REQUESTING CDC website referral information or white papers where "isolation" of SARS-CoV-2 refers to:

- the culturing of something
- performance of an amplification test (PCR) or
- the sequencing of something.

To clarify, I am requesting via disclosure all white papers / solid scientific evidence proving that:

1. the SARS-CoV-2 virus causes the illness that matches the characteristics of all of the deaths attributed to COVID-19;
2. that said virus has been properly purified / isolated from human beings, reproduced and then shown to cause said Covid-19 / SARS-COV-2 in human beings..."

Under the RTKL, a written response to your request was due on or before September 2, 2021.

Please be advised that the County does not have any records responsive to your request in its possession, under its custody or its control.

Pursuant to the Office of Open Records Final Decision in *Jenkins vs. Pennsylvania Department of State*, OOR Dkt. AP 2009-065, it should be noted that: "It is not a denial of access when an agency does not possess records and [there is no] legal obligation to obtain them (see, e.g. Section 67.506 (d)(1))." Further, an agency is not required "to create a record which does not currently exist or to compile, maintain, format or organize a record in a manner in which the agency does not currently compile, maintain, format or organize the record." 65 P.S. § 67.705.

However, you have a right to appeal this response in writing to Elizabeth Wagenseller, Executive Director, Office of Open Records (OOR), 333 Market Street, 16<sup>th</sup> Floor, Harrisburg, PA 17101-2234. If you choose to file an appeal you must do so within 15 business days of the mailing date of this response and send to the OOR: 1) this response; 2) your request; and 3) the reason why you think the record exists under the custody or control of the agency.

Also, the OOR has an appeal form available on the OOR website at: <https://www.dced.state.pa.us/public/oor/appealformgeneral.pdf>.

Sincerely,

  
By: \_\_\_\_\_  
Joshua M. Stein  
County Solicitor  
Montgomery County Solicitor's Office  
One Montgomery Plaza  
Suite 800  
Norristown, PA 19404-0311  
Phone: 610-278-3033  
Fax: 610-278-3069  
[Openrcrd@montcopa.org](mailto:Openrcrd@montcopa.org)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
Freedom of Information Office  
Building 31, Room 5B-35  
31 Center Drive, MSC 2107  
Bethesda, Maryland 20892-2107  
phone: (301) 496-5633  
fax: (301) 402-4541

Via Email: [REDACTED]

September 3, 2021

[REDACTED]

Re: FOIA Case Number: 56905

Dear [REDACTED]

This is our final response to your Freedom of Information Act (FOIA) request addressed to National Institutes of Health (NIH), dated August 18, 2021, and received in this office on the same day. You requested copies of public records that demonstrates the NIAID or NIH has a physical sample of the isolated and purified SARS-CoV-2 virus, to produce any and all evidence of this External Standard or Certified Reference Material (CRM) for calibration of RT-PCR test kits and any or all documentation and evidence of whether the Whole Genome Sequencing (WGS) occurred from the isolate, as well as evidence and information on the current modality/test being used to determine and identify the difference from the original SARS-CoV-2 virus and the "Delta Variant" and/or other variants with all evidence and documentation demonstrating the initial discovery of the other variants.

Please be advised that your request is improper as defined by FOIA given that you have not specified where (named office or institute) or what (i.e. named grant number, report, etc) you would like searched at the NIH. Considering the omission of the aforementioned information necessary for a proper search to be conducted, the NIH cannot process your request as it is written. In good faith, we provide the following information that may prove useful to you.

Much of the information on the isolation of the virus from the diseased host, which requires growth in cell culture, is already publicly available. Viruses do not replicate outside of a host or in a pure culture (devoid of other cells). Koch's postulates were formed prior to the identification of viruses as the causative agents of some diseases and also pre-date modern microbiological techniques, including the ability to isolate viruses from hosts. As such, Koch's postulates have limitations when evaluating viruses and do not adequately account for the way viruses are isolated and propagated given that viruses are obligate intracellular parasites.

SARS-CoV-2 is the virus that causes coronavirus disease 2019 (COVID-19). Active infection with SARS-CoV-2 is detected by [diagnostic tests](#). Currently there are two types of diagnostic tests – molecular tests that detect the virus's genetic material and antigen tests that detect specific proteins on the surface of the virus. For current data showing the total number of SARS-CoV-2-positive cases and deaths, visit the [CDC COVID-19 Data Tracker](#), which shows cases and deaths in the United States broken down by state and county, daily trends in the number of cases by state, and other parameters.

Evidence of SARS-CoV-2 infection can be found in a study entitled, [Pathology and Pathogenesis of SARS-CoV-2 Associated with Fatal Coronavirus Disease](#), which includes electron microscopy images of SARS-CoV-2 in infected lung and upper airway tissues as well as staining of lung and upper airway tissues using an antibody against SARS-CoV-2.

The specimens analyzed in this study were from patients with common signs and symptoms associated with COVID-19, including fever, cough, and shortness of breath. All patients had abnormal findings on chest radiographs.

There are other similar studies publicly available online. To aid in locating other related studies, please see the articles suggested in the "Similar Articles" and "Cited by" section on the manuscript's [PubMed entry](#).

The SARS-CoV-2 virus may be isolated from human clinical specimens by culturing in cells. In January 2020, CDC [isolated the SARS-CoV-2 virus](#) from a clinical specimen from the first confirmed case of COVID-19 in the United States. There are other similar studies published describing the isolation and characterization of SARS-CoV-2 from human clinical specimens. To aid in locating other related studies, please see the articles suggested in the "Similar Articles" and "Cited by" section on the manuscript's [PubMed entry](#). There are also [several publications](#) documenting SARS-CoV-2 infection and transmission among pre-symptomatic and asymptomatic individuals.

For information about the SARS-CoV-2 genome sequence, see the NIH GenBank website (<https://www.ncbi.nlm.nih.gov/genbank/sars-cov-2-seqs/>), which includes over 1 million sequences. For information about isolation, purification, amplification, and identification of the COVID-19 virus, please see the following articles <https://www.microbiologyresearch.org/content/journal/jgv/10.1099/jgv.0.001453> and refer to PubMed: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3352184/>



If you are not satisfied with the processing and handling of this request, you may contact the OD FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NIH FOIA Public Liaison

Denean Standing-Ojo  
Public Affairs Specialist  
Office of Communications and Public Liaison  
Building 31, Room 5B52S  
31 Center Drive  
Bethesda, MD 20814  
301-496-5077 (phone)  
301-496-0818 (fax)  
[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov) (email)

OGIS

National Archives and Records Admin  
8601 Adelphi Rd - OGIS  
College Park, MD 20740-6001  
202-741-5770 (phone)  
1-877-684-6448 (toll-free)  
202-741-5769 (fax)  
[ogis@nara.gov](mailto:ogis@nara.gov) (email)

In certain circumstances, provisions of the FOIA and HHS FOIA Regulations allow us to recover part of the cost of responding to your request. Because no unusual circumstances apply to the processing of your request, there are no charges for search time.

Sincerely,

*Roger Bordine*

Roger Bordine  
Freedom of Information Office, NIH

**Email Sent:** Monday, May 25, 2020 2:33 PM  
**To:** NIAID NEWS (NIH/NIAID)  
**From:** Ron Bublitz

**Subject:** a basic and serious question.

I see that you have released images of the electron microscope view of C19 virus. I would like to know how you are certain that is the virus? How was it isolated? Have you followed Koch's Postulates in order to be completely certain that is the pathogen that causes disease?

Thanks.

**Email Sent:** Jul 15, 2020, 1:26 PM  
**To:** Ron Bublitz  
**From:** NIAID NEWS (NIH/NIAID)

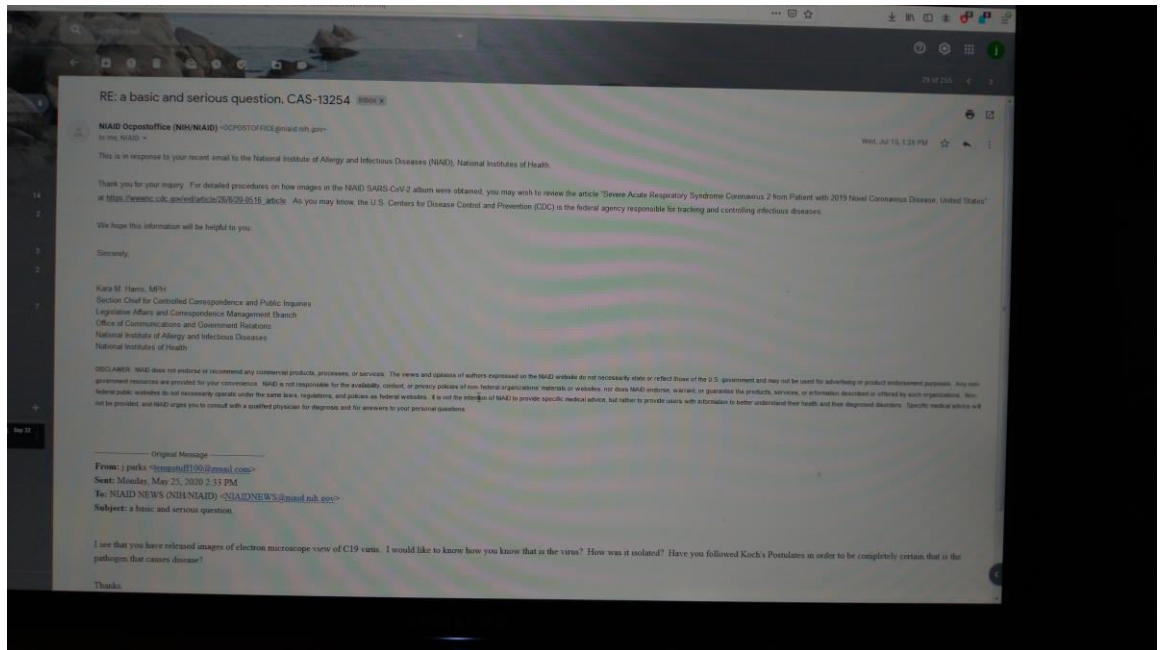
**Subject:** RE: a basic and serious question. CAS-13254

This is in response to your recent email to the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health.

Thank you for your inquiry. For detailed procedures on how images in the NIAID SARS-CoV-2 album were obtained, you may wish to review the article "Severe Acute Respiratory Syndrome Coronavirus 2 from Patient with 2019 Novel Coronavirus Disease, United States" at [https://wwwnc.cdc.gov/eid/article/26/6/20-0516\\_article](https://wwwnc.cdc.gov/eid/article/26/6/20-0516_article). As you may know, the U.S. Centers for Disease Control and Prevention (CDC) is the federal agency responsible for tracking and controlling infectious diseases.

We hope this information will be helpful to you.

Sincerely,  
Kara M. Harris, MPH  
Section Chief for Controlled Correspondence and Public Inquiries  
Legislative Affairs and Correspondence Management Branch  
Office of Communications and Government Relations  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health





## Department of Health

**KATHY HOCHUL**  
Governor

**HOWARD A. ZUCKER, M.D., J.D.**  
Commissioner

**KRISTIN M PROUD**  
Acting Executive Deputy Commissioner

September 30, 2021

William Huston  
Terra Vigilante  
P.O. Box 22  
Endicott, NY 13761

FOIL #: 21-02-070

Dear William Huston:

This letter responds to your Freedom of Information Law (FOIL) request of February 1, 2021, in which you requested “[r]ecords which indicate that the virus known as SARS-CoV-2 (a/k/a, 2019-nCoV, HCoV-19, SARSnCoV- 19, SARS-nCoV-2, and SARS2-nCoV-19) is the cause of Coronavirus Disease-2019 (COVID-19).”

The New York State Department of Health does not maintain records responsive to your request. Please be advised, the Department follows the findings and directives issued by the Centers for Disease Control and Prevention (CDC). Information responsive to your request can be found on the CDC’s website at the following link:

<https://www.cdc.gov/coronavirus/2019-ncov/your-health/about-covid-19/basics-covid-19.html>

Should you feel that you have been unlawfully denied access to records, you may appeal such denial in writing within 30 days to the Records Access Appeals Officer, Division of Legal Affairs, Empire State Plaza, 2438 Corning Tower, Albany, New York 12237-0026.

If you require additional information or wish to discuss this matter further, please do not hesitate to contact me at (518) 474-8734.

Sincerely,

*Rosemarie Hewig*

Rosemarie Hewig, Esq.  
Records Access Officer

RH/bae

March 29, 2021

To:

**Reba**

OHSU Public Records Coordinator  
Portland, OR 97239  
503-494-8231

Submitted via email to: [publicrecords@ohsu.edu](mailto:publicrecords@ohsu.edu)

Dear Ms. Reba,

This is a formal request for access to general records, made under Oregon's Public Records Law.

#### **Description of Requested Records:**

All studies and/or reports in the possession, custody or control of the Oregon Health Science University (OHSU) describing the **purification** of any "**SARS-COV-2**" (including any "variant" of "SARS-COV-2") said to have caused disease in humans (via maceration, filtration and use of an ultracentrifuge; also referred to at times by some people as "isolation"), directly from a sample taken from a diseased human, where the patient sample was not first combined with any other source of **genetic** material (i.e. monkey kidney cells aka Vero cells; fetal bovine serum).

#### **Clarifications re: the above Request**

Please note that I am not requesting studies/reports where researchers failed to **purify** the suspected "virus" and instead:

- cultured an unpurified sample or other unpurified substance, and/or
- performed an amplification test (i.e. a PCR test) on all the RNA from a patient sample or from a cell culture, or on genetic material from any unpurified substance, and/or
- sequenced the total RNA from a patient sample or from a cell culture or from any unpurified substance, and/or
- produced electron microscopy images of unpurified things.

For further clarity, please note I am already aware that according to virus theory a "virus" requires host cells in order to replicate, and I am not requesting records describing the replication of a "virus" without host cells.

Further, I am not requesting records that describe a suspected "virus" floating in a vacuum; I am simply requesting records that describe its **purification** (separation from everything else in the patient sample, as per standard laboratory practices for the purification of other small things).

Further, please also note that my request above is not limited to records that were authored by OHSU or that pertain to work done at/by OHSU. Rather, my request includes any study or report matching the above description, for example (but not limited to) a published peer-reviewed study authored by anyone, anywhere, ever, downloaded or printed by health officials at OHSU and possibly (but not necessarily) relied on as evidence of a disease-causing "virus".

If any records match the above description of requested records and are currently available to the public elsewhere, please provide enough information about each record so that I may identify and access each one with certainty (i.e. title, author(s), date, journal, where the public may access it). Please provide URLs where possible.

.

**Format:**

Pdf documents sent to me via email; I do not wish for anything to be shipped to me.

**Contact Information:**

Last name: [REDACTED]

First name: [REDACTED]

Address: [REDACTED]

Phone: [REDACTED]

Email: [REDACTED]

Thank you in advance and best wishes,

[REDACTED]





Christine Massey <cmssyc@gmail.com>

---

**Fw: Response to your supplemental questions re 03/29/21 public records request---Here you go!!!**

---

Wed, Sep 15, 2021 at 7:33 PM

Reply-To: [REDACTED]  
To: Christine Massey <cmssyc@gmail.com>

Hi Christine,

Here is the response I got from OHSU to my questions that I asked again!!!

Go ahead and make it public!!!!

Please hide my name and contact though!! :-)

Thanks for everything you do!!!!

[REDACTED]

Sent with ProtonMail Secure Email.

----- Original Message -----

On Thursday, August 28th, 2021 at 3:00 PM, Reba Kuske <[kusker@ohsu.edu](mailto:kusker@ohsu.edu)> wrote:

Good afternoon,

On Aug. 5, 2021, you submitted an email with additional questions in follow up to your closed March 29, 2021, public records request. Other than the shared documents and links provided to you with our May 6, 2021, responsive email (attached), OHSU exerts exemption under ORS 192.345(14) (Faculty Research) for any unpublished research information responsive to your supplemental questions.

The requester may seek review of OHSU's determinations to exert exemptions pursuant to ORS 192.415, 192.418, 192.422 and 192.431.

Your request will be closed. Any questions, please advise.

Reba Kuske

OHSU Public Records Coordinator

[kusker@ohsu.edu](mailto:kusker@ohsu.edu)

Cell: 503.577.2029

From: [REDACTED]  
Sent: Thursday, August 5, 2021 12:55 PM  
To: Reba Kuske <kusker@ohsu.edu>  
Subject: [EXTERNAL] RE: Re: Response to 03/29/21 public records request

Good afternoon Reba,

I have gone through the published research and although it was some useful information, the published research did not address my inquiry asking specifically if OHSU has studies and/or reports in their possession, custody or control describing the **purification** of any "SARS-COV-2" (including any "variant" of "SARS-COV-2") said to have caused disease in humans (via maceration, filtration and use of an ultracentrifuge; also referred to at times by some people as "isolation"), directly from a sample taken from a diseased human, where the patient sample was not first combined with any other source of genetic material (i.e. monkey kidney cells aka Vero cells; fetal bovine serum).

Let me reiterate that I am not requesting studies/reports where researchers failed to **purify** the suspected "virus" and instead:

- cultured an unpurified sample or other unpurified substance, and/or
- performed an amplification test (i.e. a PCR test) on all the RNA from a patient sample or from a cell culture, or on genetic material from any unpurified substance, and/or
- sequenced the total RNA from a patient sample or from a cell culture or from any unpurified substance, and/or
- produced electron microscopy images of unpurified things.

Please note I am not requesting records that describe a suspected "virus" floating in a vacuum; I am simply requesting records that describe its **purification** (separation from everything else in the patient sample, as per standard laboratory practices for the purification of other small things).

Further, please also note that my request above is not limited to records that were authored by OHSU or that pertain to work done at/by OHSU. Rather, my request includes any study or report matching the above description, for example (but not limited to) a published peer-reviewed study authored by anyone, anywhere, ever, downloaded or printed by health officials at OHSU and possibly (but not necessarily) relied on as evidence of a disease-causing "virus".

Would OHSU please let me know if they have any studies and/or reports in their possession, custody or control that describes the **purification** of any "SARS-COV-2" (including any "variant" of "SARS-COV-2") said to have caused disease in humans (via maceration, filtration and use of an ultracentrifuge; also referred to at times by some people as "isolation"), directly from a sample taken from a diseased human, where the patient sample was not first combined with any other source of genetic material (i.e. monkey kidney cells aka Vero cells; fetal bovine serum).

Thank you,

[REDACTED]

(I am attaching my original letter for ref. purpose as well)

Sent with ProtonMail Secure Email.

----- Original Message -----

On Wednesday, May 12th, 2021 at 5:24 PM, Reba Kuske <[kusker@ohsu.edu](mailto:kusker@ohsu.edu)> wrote:

Good evening,

[REDACTED]

Just let me know your questions and I will see if we can assist you.

Take care,

Reba Kuske

OHSU Public Records Coordinator

[kusker@ohsu.edu](mailto:kusker@ohsu.edu)

Cell: 503.577.2029

From:

[REDACTED]

Sent: Wednesday, May 12, 2021 4:57 PM

To: Reba Kuske <[kusker@ohsu.edu](mailto:kusker@ohsu.edu)>

Subject: [EXTERNAL] Re: Response to 03/29/21 public records request

Good evening Reba,

Thanks for the response to my Public Records Request.

I actually do have some follow up questions.

I will be emailing them to you shortly.

Thanks!

Sincerely,

[REDACTED]

Sent with ProtonMail Secure Email.

----- Original Message -----

On Thursday, May 6, 2021 8:33 AM, Reba Kuske <kusker@ohsu.edu> wrote:

Good morning, [REDACTED]

Thank you for your patience as we worked through your detailed March 29, 2021, public records request. Your request was forwarded to OHSU researchers who were noted to be actively working on COVID-related research. A number of researchers responded and OHSU hereby offers to you the following published information for your review:

· Attached article "The S1 protein of SARS-CoV2 crosses the blood-brain barrier in mice" published in the *Nature Neuroscience* dated Nov. 19, 2020.

Further, please see attached links of published research which may be useful to you:

[Baricitinib treatment resolves lower-airway macrophage inflammation and neutrophil recruitment in SARS-CoV-2-infected rhesus macaques.](#)

Hoang TN, Pino M, Boddapati AK, Viox EG, Starke CE, Upadhyay AA, Gumber S, Nekorchuk M, Busman-Sahay K, Strongin Z, Harper JL, Tharp GK, Pellegrini KL, Kirejczyk S, Zandi K, Tao S, Horton TR, Beagle EN, Mahar EA, Lee MYH, Cohen J, Jean SM, Wood JS, Connor-Stroud F, Stammen RL, Delmas OM, Wang S, Cooney KA, Sayegh MN, Wang L, Filev PD, Weiskopf D, Silvestri G, Waggoner J, Piantadosi A, Kasturi SP, Al-Shakhshir H, Ribeiro SP, Sekaly RP, Levit RD, Estes JD, Vanderford TH, Schinazi RF, Bosinger SE, Paiardini M. *Cell*. 2021 Jan 21;184(2):460-475.e21. doi: 10.1016/j.cell.2020.11.007. Epub 2020 Nov 10. PMID: 33278358 Free PMC article.

[Vascular Disease and Thrombosis in SARS-CoV-2-Infected Rhesus Macaques.](#)

Aid M, Busman-Sahay K, Vidal SJ, Maliga Z, Bondoc S, Starke C, Terry M, Jacobson CA, Wrijil L, Ducat S, Brook OR, Miller AD, Porto M, Pellegrini KL, Pino M, Hoang TN, Chandrashekar A, Patel S, Stephenson K, Bosinger SE, Andersen H, Lewis MG, Hecht JL, Sorger PK, Martinot AJ, Estes JD, Barouch DH. *Cell*. 2020 Nov 25;183(5):1354-1366.e13. doi: 10.1016/j.cell.2020.10.005. Epub 2020 Oct 9. PMID: 33065030 Free PMC article.

[Ad26 vaccine protects against SARS-CoV-2 severe clinical disease in hamsters.](#)

Tostanoski LH, Wegmann F, Martinot AJ, Loos C, McMahan K, Mercado NB, Yu J, Chan CN, Bondoc S, Starke CE, Nekorchuk M, Busman-Sahay K, Piedra-Mora C, Wrijil LM, Ducat S, Custers J, Atyeo C, Fischinger S, Burke JS, Feldman J, Hauser BM, Caradonna TM, Bondzie EA, Dagotto G, Gebre MS, Jacob-Dolan C, Lin Z, Mahrokhian SH, Nampanya F, Nityanandam R, Pessaint L, Porto M, Ali V, Benetiene D, Tevi K, Andersen H, Lewis MG, Schmidt AG, Lauffenburger DA, Alter G, Estes JD, Schuitemaker H, Zahn R, Barouch DH. Nat Med. 2020 Nov;26(11):1694-1700. doi: 10.1038/s41591-020-1070-6. Epub 2020 Sep 3. PMID: 32884153 Free PMC article.

[SARS-CoV-2 infection protects against rechallenge in rhesus macaques.](#)

Chandrashekar A, Liu J, Martinot AJ, McMahan K, Mercado NB, Peter L, Tostanoski LH, Yu J, Maliga Z, Nekorchuk M, Busman-Sahay K, Terry M, Wrijil LM, Ducat S, Martinez DR, Atyeo C, Fischinger S, Burke JS, Slein MD, Pessaint L, Van Ry A, Greenhouse J, Taylor T, Blade K, Cook A, Finneyfrock B, Brown R, Teow E, Velasco J, Zahn R, Wegmann F, Abbink P, Bondzie EA, Dagotto G, Gebre MS, He X, Jacob-Dolan C, Kordana N, Li Z, Lifton MA, Mahrokhian SH, Maxfield LF, Nityanandam R, Nkolola JP, Schmidt AG, Miller AD, Baric RS, Alter G, Sorger PK, Estes JD, Andersen H, Lewis MG, Barouch DH. Science. 2020 Aug 14;369(6505):812-817. doi: 10.1126/science.abc4776. Epub 2020 May 20. PMID: 32434946 Free PMC article.

Lastly, please following this link to review the recent study which confirms virus variants reduce protection against COVID-19: <https://news.ohsu.edu/2021/04/20/study-confirms-virus-variants-reduce-protection-against-covid-19>.

OHSU exerts exemption under ORS 192.345(14) (Faculty Research) for any related, unpublished research information. The requester may seek review of OHSU's determinations to exert exemptions pursuant to ORS 192.415, 192.418, 192.422 and 192.431.

Please email if you have any questions. Otherwise, your request is now closed.

Have a wonderful rest of your week.

Thank you,

Reba Kuske

OHSU Public Records Coordinator

[kusker@ohsu.edu](mailto:kusker@ohsu.edu)

Cell: 503.577.2029



**From:** [REDACTED]  
**To:** [OHA.PublicRecords@state.or.us](mailto:OHA.PublicRecords@state.or.us)  
**Subject:** Public Records request to OHA re: "SARS-COV-2" purification  
**Date:** Monday, March 29, 2021 4:06:59 PM

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

March 29, 2021

To:

Keely West, JD  
Central Operations Manager  
503-945-6292

Jeanne Windham  
Public Records Coordinator  
971-345-1688

Submitted via email to: [OHA.PublicRecords@state.or.us](mailto:OHA.PublicRecords@state.or.us)

Dear Ms. West and Ms. Windham,

This is a formal request for access to general records, made under Oregon's Public Records Law.

**Description of Requested Records:**

All studies and/or reports in the possession, custody or control of the Oregon Health Authority (OHA) describing the purification of any "SARS-COV-2" (including any "variant" of "SARS-COV-2") said to have caused disease in humans (via maceration, filtration and use of an ultracentrifuge; also referred to at times by some people as "isolation"), directly from a sample taken from a diseased human, where the patient sample was not first combined with any other source of genetic material (i.e. monkey kidney cells aka Vero cells; fetal bovine serum).

**Clarifications re: the above Request**

Please note that I am not requesting studies/reports where researchers failed to **purify** the suspected "virus" and instead:

- cultured an unpurified sample or other unpurified substance, and/or
- performed an amplification test (i.e. a PCR test) on all the RNA from a patient sample or from a cell culture, or on genetic material from any unpurified substance, and/or
- sequenced the total RNA from a patient sample or from a cell culture or from any unpurified substance, and/or
- produced electron microscopy images of unpurified things.

For further clarity, please note I am already aware that according to virus theory a "virus" requires



host cells in order to replicate, and I am not requesting records describing the replication of a "virus" without host cells.

Further, I am not requesting records that describe a suspected "virus" floating in a vacuum; I am simply requesting records that describe its purification (separation from everything else in the patient sample, as per standard laboratory practices for the purification of other small things).

Further, please also note that my request above is not limited to records that were authored by the OHA or that pertain to work done at/by OHA. Rather, my request includes any study or report matching the above description, for example (but not limited to) a published peer-reviewed study authored by anyone, anywhere, ever, downloaded or printed by health officials at OHA and possibly (but not necessarily) relied on as evidence of a disease-causing "virus".

If any records match the above description of requested records and are currently available to the public elsewhere, please provide enough information about each record so that I may identify and access each one with certainty (i.e. title, author(s), date, journal, where the public may access it). Please provide URLs where possible.



**Format:**

Pdf documents sent to me via email; I do not wish for anything to be shipped to me.

**Contact Information:**

Last name: [REDACTED]

First name: [REDACTED]

Address: [REDACTED]

Phone: [REDACTED]

Email: [REDACTED]

Thank you in advance and best wishes,  
[REDACTED]

On Tuesday, March 30, 2021 1:28 PM, Windham Jeanne  
<JEANNE.WINDHAM@dhsosha.state.or.us> wrote:

VIA EMAIL ONLY - [REDACTED]

March 30, 2021

[REDACTED]

Re: Public Records Request - Studies/Reports Related to Purification of Any  
"SARS-COV-2 Causing Disease in Humans (2021-[REDACTED])

Good Afternoon [REDACTED],

This will confirm Oregon Health Authority received your March 29, 2021 public records request for "All studies and/or reports in the possession, custody or control of the Oregon Health Authority (OHA) describing the purification of any "SARS-COV-2" (including any "variant" of "SARS-COV-2") said to have caused disease in humans (via maceration, filtration and use of an ultracentrifuge; also referred to at times by some people as "isolation"), directly from a sample taken from a diseased human, where the patient sample was not first combined with any other source of genetic material (i.e. monkey kidney cells aka Vero cells; fetal bovine serum)." **There are no responsive records to your request. This will complete your request.**

**Jeanne Windham**

Public Records and Internal Litigation Process Coordinator

OREGON HEALTH AUTHORITY

Fiscal and Operations Division

500 Summer St. NE, E-20

Salem, OR 97301

(971) 345-1688

[jeanne.windham@dhsosha.state.or.us](mailto:jeanne.windham@dhsosha.state.or.us)

<http://www.oregon.gov/OHA>



September 1, 2021

[REDACTED]  
King of Prussia, PA [REDACTED]

[ladymohan@yahoo.com](mailto:ladymohan@yahoo.com)

**RE: Right to Know Law Request  
DOH-RTKL-COV-150-2021**

Dear M [REDACTED]

This letter acknowledges receipt by the Pennsylvania Department of Health (Department) of your written request for records under the Pennsylvania Right-to-Know Law (RTKL), 65 P.S. §§ 67.101-67.3104. The Department received your request on August 25, 2021. You requested:

[A]ny records that describe the isolation of a "COVID-19 virus" (aka "SARS-CoV-2") from an unadulterated sample taken from a diseased human, where the patient sample was not first combined with any other source of genetic material. Isolate meaning a thing is separated from all other material surrounding it. I am NOT REQUESTING white papers where "isolation" of SARS-CoV-2 refers to: the culturing of something, performance of an amplification test (PCR) or the sequencing of something.

Your request is denied, as the Department is not in possession of records responsive to your request.

As a courtesy, the Department provides the following information: The Department interprets your request to seek records for the isolation of intact virus/viral particles of SARS-CoV-2.

Please be advised that the Department's molecular test processing is not isolating live virus or viral particles. The Department is isolating SARS-CoV-2 genetic material extracted from virus/viral particles in the patient specimen. That extracted genetic material is used in PCR reactions for the detection of the presence of SARS-CoV-2 genetic material in that extract.

The Department's Bureau of Laboratories utilizes COVID PCR assays which have received authorized EUAs from the FDA:

- (1) The CDC COVID RT-PCR assay described in the most recent approved update; and
- (2) The ThermoFisher COVID multiplex RT-PCR panel assay.

September 1, 2021

Please be advised that the Department does not possess information for all EUAs. However, FDA approved EUAs are publicly available for free by following this link:

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>.

Please be advised that this correspondence will serve to close this record with our office as permitted by law.

Sincerely,

A handwritten signature in black ink that reads "Lisa M. Keefer". The signature is written in a cursive, flowing style.


Lisa M. Keefer  
Agency Open Records Officer  
Pennsylvania Department of Health  
625 Forster Street  
825 Health and Welfare Building  
Harrisburg, PA 17120-0701

Date of Mailing: 09/01/2021



Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30333

November 2, 2020



This letter is in response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of August 9, 2020, for “All records in the possession, custody or control of The Centers for Disease Control (CDC) describing the isolation of a SARS-COV-2 virus, directly from a sample taken from a diseased patient, where the patient sample was not first combined with any other source of genetic material (i.e. monkey kidney cells aka vero cells; lung cells from a lung cancer patient).

Please note that I am using "isolation" in the every-day sense of the word: the act of separating a thing(s) from everything else. I am not requesting records where "isolation of SARS-COV-2" refers instead to:

- \* the culturing of something,
- \* or the performance of an amplification test (i.e. a PCR test),
- \* or the sequencing of something.

Please also note that my request is not limited to records that were authored by the CDC or that pertain to work done by The CDC. My request includes any sort of record, for example (but not limited to) any published peer-reviewed study that the CDC has downloaded or printed.

If any records match the above description of requested records and are currently available to the public elsewhere, please provide enough information about each record so that I may identify and access each record with certainty (i.e. title, author(s), date, journal, where the public may access it).”

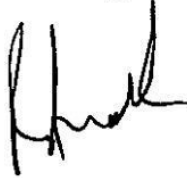
A search of our records failed to reveal any documents pertaining to your request.

You may contact our FOIA Public Liaison at 770-488-6277 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at [ogis@nara.gov](mailto:ogis@nara.gov); telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.



If you are not satisfied with the response to this request, you may administratively appeal by writing to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201. You may also transmit your appeal via email to [FOIARequest@psc.hhs.gov](mailto:FOIARequest@psc.hhs.gov). Please mark both your appeal letter and envelope "FOIA Appeal." Your appeal must be postmarked or electronically transmitted by Monday, February 1, 2021.

Sincerely,

A handwritten signature in black ink, appearing to read 'Roger Andoh', with a stylized, cursive script.

Roger Andoh  
CDC/ATSDR FOIA Officer  
Office of the Chief Operating Officer  
(770) 488-6399  
Fax: (404) 235-1852

#20-02166-FOIA





Christine Massey <cmssyc@gmail.com>

---

**Fwd: HHS FOIA Request 2021-01625-FOIA-OS**

---

Mon, Aug 23, 2021 at 6:05 PM

To: "christinem@fluoridefreepeel.ca" <christinem@fluoridefreepeel.ca>

You can add to your list. From US Department of Human and Health Services.

----- Forwarded message -----

From: **Taylor, Natasha** <foiarequest@hhs.gov>

Date: Thu, Aug 19, 2021 at 4:50 PM

Subject: HHS FOIA Request 2021-01625-FOIA-OS

To: [REDACTED]

RE: 2021-01625-FOIA-OS

Mr. [REDACTED]

Dear Mr. [REDACTED]

This is in response to your Freedom of Information Act (FOIA) request, dated: **August 18, 2021**, concerning "Records that demonstrates the US Department of Health and Human Services has a physical sample of the isolated and purified SARS-CoV-2 virus including the following: 1) Any and all evidence of this External Standard or Certified Reference Material (CRM) for calibration of RT-PCR test kits and any or all documentation; 2) Evidence of whether the Whole Genome Sequencing (WGS) occurred from the isolate; 3) Evidence and information on the current modality/test being used to determine and identify the difference from the original SARS-CoV-2 virus and the "Delta Variant" and/or other variants with all evidence and documentation demonstrating the initial discovery of the other variants. (Date Range for Record Search: From 10/1/2019 To 8/18/2021)".

We received your request on **August 18, 2021**.

For administrative convenience and to fully respond to your request, program staff have provided the following information below with corresponding web links.

SARS-CoV-2 is the virus that causes coronavirus disease 2019 (COVID-19). Active infection with SARS-CoV-2 is detected by [diagnostic tests](#). Currently there are two types of diagnostic tests – molecular tests that detect the virus's genetic material and antigen tests that detect specific proteins on the surface of the virus. For current data showing the total number of SARS-CoV-2-positive cases and deaths, visit the [CDC COVID-19 Data Tracker](#), which shows cases and deaths in the United States broken down by state and county, daily trends in the number of cases by state, and other parameters.

Evidence of SARS-CoV-2 infection can be found in a study entitled, [Pathology and Pathogenesis of SARS-CoV-2 Associated with Fatal Coronavirus Disease](#), which includes electron microscopy images of SARS-CoV-2 in infected lung and upper airway tissues as well as staining of lung and upper airway tissues using an antibody against SARS-CoV-2.

The specimens analyzed in this study were from patients with common signs and symptoms associated with COVID-19, including fever, cough, and shortness of breath. All patients had abnormal findings on chest radiographs.

There are other similar studies publicly available online. To aid in locating other related studies, please see the articles suggested in the "Similar Articles" and "Cited by" section on the manuscript's [PubMed entry](#).

The SARS-CoV-2 virus may be isolated from human clinical specimens by culturing in cells. In January 2020, CDC [isolated the SARS-CoV-2 virus](#) from a clinical specimen from the first confirmed case of COVID-19 in the United States. There are other similar studies published describing the isolation and characterization of SARS-CoV-2 from human clinical specimens. To aid in locating other related studies, please see the articles suggested in the "Similar Articles" and "Cited by" section on the manuscript's [PubMed entry](#). There are also [several publications](#) documenting SARS-CoV-2 infection and transmission among pre-symptomatic and asymptomatic individuals.

For information about the SARS-CoV-2 genome sequence, see the NIH GenBank website (<https://www.ncbi.nlm.nih.gov/genbank/sars-cov-2-seqs/>), which includes over 44,000 sequences as of December 7, 2020.

If you need any further assistance or would like to discuss any aspect of the records provided please contact either our FOIA Requester Service Center at 770-488-6399 or our FOIA Public Liaison at 770-488-6277.

Sincerely,

Natasha Taylor  
Government Information Specialist  
Main Office Line: 202-690-7453

## FOIA REQUEST: records re PURIFICATION OF “SARS-COV-2”

August 26<sup>th</sup>, 2021

Attn: FOIA Request  
Department of General Services  
c/o Division of Consolidated Laboratory Services  
1100 Bank Street, Suite 420  
Richmond, VA 23219  
FOIA\_DGS@dgs.virginia.gov

FOIA\Custodian of Records: This is a formal request for access to general records, reports, reference request forms. In accordance with the Department of General Services Responsibilities in Responding to Requests, The Department of General Services must respond to this request within five working days of receipt. "Day One" is the day after the request is received. The five-day period does not include weekends or holidays. made under Virginia's Freedom of Information Act.

If it is practically impossible to respond to the request within five days, please state in writing and explain the conditions which make the response impossible. An additional seven working days to respond to the request, gives the Department of General Services a total of 12 working days to respond, which follows procedure.

### Description of Requested Records:

All studies and/or reports in the possession, custody or control of the Division of Consolidated Laboratory Services (DCLS) describing the **purification** of any “**COVID-19 virus**” (aka “SARS-COV-2”, including any alleged “variants” i.e. “B.1.1.7”, “B.1.351”, “P.1”) directly from a sample taken from a diseased human, where the patient sample was not first combined with any other source of **genetic** material (i.e. monkey kidney cells aka Vero cells; fetal bovine serum).

Please note that I am not requesting studies/reports where scientists and researchers failed to **purify** the suspected “virus” (separate the alleged “virus” from everything thing else in the patient sample) and instead:

- cultured an unpurified sample or other unpurified substance, and/or
- performed an amplification test (i.e. a PCR test) on the total RNA from a patient sample or from a cell culture, or on genetic material from any unpurified substance, and/or
- fabricated a genome based on PCR-detected sequences in the total RNA from a patient sample or from a cell culture or from any unpurified substance, and/or
- produced electron microscopy images of unpurified things in a cell culture.

### Clarification of Request

For further clarity, please note I am already aware that according to virus theory a "virus" requires host cells in order to replicate, and I am **not** requesting records describing the **replication** of a "virus" without host cells.

Further, I am **not** requesting records that describe a suspected "virus" floating in a vacuum; I am simply requesting records that describe its **purification** (separation from everything else in the human patient sample, as per standard operating procedure the Virology section at DCLS or laboratory practices for the purification of other very small things).

Please note that my request includes any study/report matching the above description, for example (but not limited to) any published peer-reviewed study authored by anyone, anywhere that DCLS is aware of.

Please also note that despite the fact that purification is an essential (but not sufficient) step in proving the existence of a disease-causing "virus", as of today 98 institutions globally (including the U.S. CDC, Public Health Agency of Canada, Australian Department of Health, New Zealand Ministry of Health, European Centre for Disease Prevention and Control, UK Department for Health and Social Care, Indian Council of Medical Research) have all failed to provide or cite any such records, therefore to my knowledge no such records exist and if they do exist I cannot access them until I am provided a citation or URL.

Therefore in the interest of citizens of the Commonwealth of Virginia and transparency and in accordance with the purposes of the legislation (Virginia's Freedom of Information Act), if any records match the above description of requested records and are currently available to the public elsewhere, please provide enough information about each record so that I may identify and access each one with certainty (i.e. title, author(s), date, journal, where the public may access it). Please provide URLs where possible.

### Format:

Pdf documents sent to me via email; I do not wish for anything to be shipped to me.

### Contact Information:

Last name: [REDACTED]

First name: [REDACTED]

Address: [REDACTED]

Phone: [REDACTED]

Email: [REDACTED]



**COMMONWEALTH of  
VIRGINIA**  
*Department of General Services*

Joseph F. Damico  
Director

Sandra Gill,  
Deputy Director

Matthew James,  
Deputy Director

1100 Bank Street  
Suite 420  
Richmond, Virginia 23219  
Phone (804) 786-3311  
FAX (804) 371-8305

September 2, 2021

Via email: [REDACTED]

Dear [REDACTED]

I am responding to your request for information received by the Department of General Services (DGS) via email on August 26, 2021. In your request you asked for in brief, all studies and/or reports in possession, custody or control of the Division of Consolidated Laboratory Services describing the **purification** of any **COVID-19 virus**.

Please find attached documents responsive to your request.

I hope this information is helpful. Thank you for your inquiry.

Sincerely,

Dena Potter  
Director of Communications

/Attachments

**CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel**

**I. PURPOSE/APPLICATION:**

- A. This procedure is for the qualitative detection of nucleic acid from the 2019-novel Coronavirus (nCoV), termed severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), using real-time reverse transcription polymerase chain reaction (RT-PCR) amplification. Testing is performed for the purpose of patient diagnosis and surveillance of COVID-19 illness within Virginia at the direction of the Virginia Department of Health.
- B. The RT-PCR test is intended for the qualitative detection of nucleic acid from SARS-CoV-2 in upper and lower respiratory specimens collected from individuals who meet clinical and/or epidemiological criteria. Testing in the United States is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests by trained laboratory personnel who are proficient in performing real-time RT-PCR assays. The CDC 2019-nCoV RT-PCR Diagnostic Panel is only for use under a Food and Drug Administration (FDA) Emergency Use Authorization (EUA).

**II. SUMMARY/SCOPE:**

- A. The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis of COVID-19 illness, and is based on widely used nucleic acid amplification technology. The diagnostic panel contains oligonucleotide primers and dual-labeled hydrolysis probes (TaqMan®) for the detection of SARS-CoV-2 RNA in respiratory specimens.
- B. The SARS-CoV-2 oligonucleotide primers and probes target regions of the virus nucleocapsid (N) gene. Oligonucleotide primers and probe that target the human RNase P gene (RP) in human clinical specimens is included in the panel as an assay control to assess specimen integrity and assay performance. Purified RNA isolated from upper and lower respiratory specimens is reverse transcribed to cDNA and amplified in the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with SDS version 1.4 software. If viral RNA is present in the clinical specimen, then the assay probes will anneal to specific target sequences located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle by the Applied Biosystems 7500 Fast Dx Real-Time PCR instrument. Detection of viral RNA provides clinical, epidemiological and surveillance information for SARS-CoV-2.



- C. Quality is assured through testing of positive and negative PCR controls along with a Human Specimen Control (HSC) as an extraction control and an RP within each clinical specimen.
- D. DCLS validated three extraction methods for this procedure including:
  - 1. Qiagen QIAamp DSP Viral RNA Mini Kit or QIAamp Viral RNA Mini Kit
  - 2. MagMax Viral/Pathogen Nucleic Acid Isolation Kit using the ThermoFisher Kingfisher Flex Magnetic Particle Processors with 96 deep well head extraction platform
  - 3. Perkin Elmer's Chemagic™ Viral DNA/RNA 300 Isolation Kit using Perkin Elmer Chemagic™360 Magnetic Bead extraction platform

### III. **SAMPLE COLLECTION:**

- A. Specimen Type:
  - 1. Sample types acceptable for testing:
    - a. upper and lower respiratory specimens
      - i. nasopharyngeal or oropharyngeal swabs
      - ii. sputum
      - iii. lower respiratory tract aspirates
      - iv. bronchoalveolar lavage
      - v. nasopharyngeal wash/aspirate or nasal aspirates
    - b. respiratory specimens collected from individuals who meet 2019-nCoV clinical and/or epidemiological criteria. For example:
      - i. clinical signs and symptoms associated with 2019-nCoV infection
      - ii. contact with a probable or confirmed 2019-nCoV case
      - iii. history of travel to geographic locations where 2019-nCoV cases were detected
      - iv. other epidemiologic links for which 2019-nCoV testing may be indicated as part of a public health investigation
  - 2. Swab specimens should be collected using only swabs with a synthetic tip, such as nylon or Dacron®, and an aluminum or plastic shaft. Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended.
  - 3. Place swabs immediately into sterile tubes containing 1-3 ml of appropriate transport media, such as viral transport media (VTM), Ames transport medium, phosphate buffered saline, or sterile saline.
- B. Handling and Shipping Conditions:
  - 1. Specimens can be stored at 2-8 °C for up to 72 hours after collection.
  - 2. Transport to DCLS refrigerated on ice packs.
  - 3. The DCLS COVID-19 Submission Form (Qualtrax ID # 34293) is the preferred form to submit specimens for testing. However, the DCLS Test Request Form (Qualtrax ID #16857) can also be used.
  - 4. The DCLS Clinical Microbiology/Virology Request Form (Qualtrax ID #

16857) has been discontinued, but will be accepted if submitted with specimens.

5. The submission form should be fully completed by the submitter and submitted with the specimen; OR the submitter may use Webvision or DCLS Connect to electronically enter information for specimen submission. Information necessary for proper specimen submission:
  - a. Patient Information (name, address, age or date of birth)
  - b. Submitter Information (name, address, telephone number)
  - c. Patient Medical History (information relevant to diagnosis such as symptoms, date of onset, recent exposures, travel history)
  - d. Outbreak Information, if applicable, (outbreak number, role of patient in outbreak)
  - e. Test requested, specimen source, and date collected

When specimens are received in Sample Support Services (SSS), a LIMS identification number will be assigned. The patient information and specimen metadata will be entered into LIMS, labels will be generated and placed on the specimen container and appropriate paperwork. The specimens will be stored refrigerated in a SSS refrigerated until retrieved by testing personnel, or the specimens will be delivered to the COVID extraction laboratory (room 268 A or B).

C. Storage Conditions:

1. When specimen is received at DCLS, store at 2-8 °C for up to 72 hours after collection.
2. If a delay in extraction is expected, store specimens at -70°C or lower.
3. Store extracted nucleic acid at -70°C or lower.
4. Maintain RNA on a cold block or on ice during preparation to ensure stability.
5. After testing is completed, specimens that are positive for SARS-CoV-2 will be aliquotted into cryovials and stored at -70°C or lower for long term storage, for at least three years. Samples must be disposed of as biohazardous waste in a red waste bin.
6. *Chain of Custody (COC) samples are discarded according to Evidence Receipt/Storage and Disposition Procedure (Qualtrax ID # 1804)*

D. Rejection Criteria:

1. After consultation with the Senior Scientist, Principal Scientist, Lead Scientist, or Group Manager, samples meeting the rejection criteria outlined below may still be tested and reported with additional disclaimers.
  - a. Absence of or inconsistent labeling and identification:
    - i. The absence of a name or unique identifier on specimen container.
    - ii. More than one name on specimen container.
    - iii. Name on paperwork is different from name on specimen

container.

- b. Specimen submission form not properly filled out (e.g. patient name or address missing, etc.).
- c. Specimen received in expired viral transport medium.
- d. Specimen received without refrigeration.
- e. Specimen received at the laboratory more than 72 hours after collection date.
- f. Specimen with insufficient volume for testing.
- g. When a sample is deemed unacceptable for testing, the submitter will receive a LIMS report explaining the reason for specimen rejection (Unsatisfactory for testing - reason).

#### **IV. PERSONNEL QUALIFICATIONS:**

- A. *Procedures in Molecular Detection and Characterization Group (MDC) may only be performed by approved testing personnel. The list of testing personnel can be found in the DCLS Training Matrix. Testing personnel must comply with DCLS Competency (Qualtrax ID # 16472). Personnel will demonstrate competency twice during the first year. Competency assessment, with documentation, will be performed annually in subsequent years.*

#### **V. INTERFERENCES/LIMITATIONS OF PROCEDURE:**

- A. This test has not been FDA cleared or approved; this test has been authorized by FDA under a EUA for use by laboratories certified under CLIA, 42 U.S.C. § 263a, to perform high complexity tests.
- B. This test has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens.
- C. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb3(b)(1), unless the authorization is terminated or revoked sooner.
- D. Amplification technologies such as PCR are sensitive to accidental introduction of PCR product from previous amplification reactions. Incorrect results could occur if either the clinical specimen or the real-time PCR reagents used in the amplification step become contaminated by accidental introduction of amplification product (amplicon). To mitigate this limitation, workflow in the laboratory proceeds in a unidirectional manner.
- E. Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false test results. Training in specimen collection is highly recommended due to the importance of specimen quality.
- F. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by SARS-CoV-2 have not been determined. Collection of multiple

specimens (types and time points) from the same patient may be necessary to detect the virus.

- G. A false-negative result may occur if a specimen is improperly collected, transported or handled. False-negative results may also occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the specimen.
- H. Positive and negative predictive values are highly dependent on prevalence. False-negative test results are more likely when prevalence of disease is high. False-positive test results are more likely when prevalence is moderate to low.
- I. If the virus mutates in the rRT-PCR target region, SARS-CoV-2 may not be detected or may be detected less predictably. Inhibitors or other types of interference may produce a false-negative result. An interference study evaluating the effect of common cold medications was not performed.
- J. Test performance can be affected because the epidemiology and clinical spectrum of infection caused by SARS-CoV-2 is not fully known. For example, clinicians and laboratories may not know the optimum types of specimens to collect, and, during the course of infection, when these specimens are most likely to contain levels of viral RNA that can be readily detected.
- K. Detection of viral RNA may not indicate the presence of infectious virus or that SARS-CoV-2 is the causative agent for clinical symptoms.
- L. The performance of this test has not been established for monitoring treatment of COVID-19 infection.
- M. This test cannot rule out diseases caused by other bacterial or viral pathogens.

## **VI. SAFETY:**

- A. Attire and Personal Protective Equipment
  - 1. *Totally enclosed shoes are required in this laboratory at all times.*
  - 2. *The required minimum Personal Protective Equipment (PPE) in this laboratory is a lab coat and safety glasses.*
  - 3. *Gloves are required when handling samples, infectious agents, chemicals, closing and moving regulated medical waste containers, and when working in a biological safety cabinet (BSC) or chemical fume hood. Nitrile gloves are preferred.*

*NOTE: If latex gloves are in use, an alternative, non-latex glove must be available and laboratory door signage must reflect the usage of latex gloves.*

- 4. Additional PPE that should be used when performing nucleic acid extractions, automated instrument loading, and specimen archiving in a Biosafety Level-2 (BSL-2) laboratory include:
  - fluid-impervious, back-closing gowns

- double gloves when working in the BSC
  - face shields (if safety glasses fog due to face masks)
  - disposable face masks
5. Additional PPE that should be used when performing nucleic acid extractions of lower respiratory specimens in a Biosafety Level-3 (BSL-3) laboratory include:
- respirators: PAPR or CAPR, N-95 with safety glasses
  - fluid-impervious, back-closing gowns
  - double gloves when working in the BSC
- B. *Safety precautions must be taken when handling reagents, samples, and equipment in this laboratory.*
- C. Special Precautions
1. BSL-2+ work practices will be used in BSL-2 testing laboratories.
  2. Lower respiratory specimens will be processed in a BSL-3 laboratory, using BSL-3 safety and work practices.
  3. Vortex mixing will occur inside of the BSC.
  4. Sealed rotors will be used for centrifugation steps, and will only be opened inside of a BSC.
  5. Vacuum manifolds will only be used inside of the BSC.
  6. All items will be decontaminated prior to removal from the BSC.
  7. Specimen containers are only opened inside of a BSC prior to inactivation via lysis buffer treatment for at least 10 minutes. Inactivated specimens may be removed from the BSC for loading onto the instrument.
  8. Closed specimen tubes can be handled on the benchtop for plate mapping preparations.
  9. Sharp items are discarded in sharps containers. Broken glass is discarded in a broken glass box and the box should not be filled more than 3/4 full. If broken glass has come in contact with a sample then it is discarded in a sharps container. When ready to discard a sharps container, close the top securely and place it in a red regulated medical waste bin, or in the post lab, a designated cardboard box labeled with “regulated medical waste”.
- D. Location of Eye Wash and Emergency Shower
1. *An eye wash/drench hose is present on each sink in this laboratory.*
  2. *The emergency shower is located in room 250/IV and MDC/134.*
- E. Hazards Associated With Procedure

## 1. Chemical Hazards

*The following toxic, carcinogenic, or highly hazardous,  $\leq 2$ , chemicals are associated with this procedure:*

Chemical Name	Health Hazards	Flammability	Reactivity	Oxidizing Solid/Liquid	Corrosive to Metals	Environmental Hazards	Fume Hood Required
Qiagen Buffer AVL*	1	N/A	N/A	N/A	N/A	3	No
Qiagen Buffer AW1*	2	N/A	N/A	N/A	N/A	N/A	No
Ethanol	2	2	N/A	N/A	N/A	N/A	No
Proteinase K	1	N/A	N/A	N/A	N/A	N/A	No
BTL, Viral/Pathogen Binding Solution	1	N/A	N/A	N/A	N/A	3	No
MagMax Viral/Pathogen Proteinase K	1	N/A	N/A	N/A	N/A	N/A	No
BTL, Viral/Pathogen Wash Buffer	2	N/A	N/A	N/A	N/A	N/A	No

\*Contains chaotropic salt. Not compatible with disinfectants containing bleach.

## 2. Biological Hazards

- a. Respiratory viruses, including influenza, SARS-CoV-2, and other viruses, are human pathogens.
- b. All clinical specimens will be handled as potentially infectious materials using Universal Precautions as specified in the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030, [www.osha.gov](http://www.osha.gov)). Only personnel trained in handling infectious materials will be permitted to perform this procedure.
- c. Aerosol barrier pipette tips will be used to prevent the generation of aerosols. Wash hands thoroughly after handling specimens, reagents, and equipment, after removing gloves, and before leaving the laboratory. Disinfect all bench tops and BSC after work is complete.
- d. Specimen coolers and packages containing COVID-19 specimens are opened on the benchtop by SSS staff. Samples are then placed inside of the BSC for accessioning. All sample tubes are decontaminated prior to removal from the BSC and delivery to the testing laboratory.



3. Radiological Hazards  
*The following radiological hazards are associated with this procedure:  
Not Applicable.*
4. Safety Data Sheets/Pathogen Safety Data Sheets  
*The laboratory is responsible for maintaining a current, complete file of Safety Data Sheets (SDSs) related to this procedure. The SDSs are available to the analyst on computers throughout the laboratory at the following URL: <https://msdsmanagement.msdsonline.com/21943a72-obc7-4000-a405-4ba03280a52c/ebinder/?nas=True>*

F. Spill Response

1. *Small spills - handled by the laboratory staff (refer to SDS) or call Administration for Spill Response Team notification.*
2. *Large spills – call Administration for Spill Response Team notification.*

*Refer to DCLS Safety Manual (Qualtrax ID # 1805) for additional safety information.*

## VII. EQUIPMENT & SUPPLIES, REAGENTS & STANDARDS:

*For labeling requirements for purchased or prepared media/reagents/standards, refer to Measurement and Data Traceability (Qualtrax ID # 1789).*

A. Equipment & Supplies: Store at room temperature unless otherwise specified

1. Specimen Extraction
  - a. Qiagen QIamp DSP Viral RNA or QIamp Viral RNA
    - i. QIAamp Mini Spin Columns with Wash Tubes. Store dry at 2–8°C
    - ii. Elution Tubes (1.5 ml)
    - iii. Lysis Tubes (2 ml)
    - iv. Wash Tubes (2 ml)
    - v. 1.5 ml microcentrifuge tubes
    - vi. Sterile, RNase-free pipets
    - vii. Sterile, RNase-free pipet tips with aerosol barriers
    - viii. Microcentrifuge (with rotor for 1.5 ml and 2 ml tubes)
    - ix. For vacuum protocols:
      - a) QIAvac 24 Plus vacuum manifold (cat. no. 19413) or equivalent
      - b) VacConnectors (cat. no. 19407)
      - c) Vacuum Regulator (cat. no. 19530) for easy monitoring of vacuum pressures and easy releasing of vacuum
      - d) Vacuum Pump (cat. no. 84010 or equivalent pump capable

- of producing a vacuum of –800 to –900 mbar)
- e) Optional: VacValves (cat. no. 19408)
- f) Optional: QIAvac Connecting System (cat. no. 19419)

b. Altria's Kingfisher Flex Magnetic Particle Processor with 96 deep well head extraction platform for use with MagMax Viral/Pathogen Nucleic Acid Isolation Kit.

- i. KingFisher™ deep-well 96 plate KingFisher Duo cap for elution strip
- ii. Adjustable micropipettors
- iii. Multi-channel micropipettors
- iv. MicroAmp™ Clear Adhesive Film
- v. Conical Tubes (15 mL)
- vi. Conical Tubes (50 mL)
- vii. Reagent reservoirs
- viii. Nonstick, RNase-Free Microfuge Tubes, 1.5 mL
- ix. Nonstick, RNase-Free Microfuge Tubes, 2.0 mL
- x. Vortex
- xi. 96 deep-well magnetic head
- xii. 96 deep-well heat block

c. Perkin Elmer's Chemagic™ Viral DNA/RNA 300 Isolation Kit using Perkin Elmer Chemagic™360 Magnetic Bead extraction platform.

- i. Rack with Disposable Tips
- ii. low-well-plate (MICROTITER SYSTEM)
- iii. Magnetic Beads
- iv. deep-well-plate (riplate SW)

2. PCR Set up and Detection

- a. Vortex mixer
- b. Microcentrifuge
- c. Micropipettes (2 or 10 µL, 200 µL and 1000 µL)
- d. Multichannel micropipettes (5-50 µl)
- e. Racks for 1.5 mL microcentrifuge tubes
- f. 2 x 96-well -20°C cold blocks
- g. 7500 Fast Dx Real-Time PCR Systems with SDS 1.4 software
- h. Molecular grade water, nuclease-free
- i. 10% bleach (1:10 dilution of commercial 5.25-6.0% hypochlorite bleach)
- j. DNAZap™ or equivalent
- k. RNase AWAY™ or equivalent
- l. Aerosol barrier pipette tips
- m. 1.5 mL microcentrifuge tubes (DNase/RNase free)
- n. 0.2 mL PCR reaction plates
- o. MicroAmp Optical 8-cap Strips

B. Reagents:

1. Specimen Extraction; All solutions should be stored at room temperature (15–25°C) unless otherwise stated. Follow manufacturer expiry dates.

- a. Qiagen QIAmp DSP Viral RNA Mini Kit and QIAamp® Viral RNA Mini Kit:

The following reagents are stored at room temperature and expire per the kit expiration date:

- i. Buffer AVL
- ii. Buffer AW1 (concentrate)
- iii. Buffer AW2 (concentrate)
- iv. Buffer AVE
- v. Carrier RNA (poly A);
  - a) Store at room temperature (15–25°C)
  - b) Dissolve in 310 µl Buffer AVE. **Note:** This solution should be prepared fresh, and is stable at 2–8°C for up to 48 hours. Buffer AVE–carrier RNA develops a precipitate when stored at 2–8°C that must be re-dissolved by warming at 80°C ±3°C before use.
  - c) Unused portions of carrier RNA dissolved in Buffer AVE should be frozen in aliquots at –25°C to –15°C. Do not freeze–thaw the aliquots of carrier RNA more than 3 times. DO NOT warm Buffer AVL–carrier RNA solution more than 6 times. DO NOT incubate at 80°C for more than 5 minutes. Frequent warming and extended incubation will cause degradation of the carrier RNA, leading to reduced recovery of viral RNA and eventually to false negative RT-PCR results, particularly when low-titer samples are used.
- vi. Ethanol (96–100%)

Store the following at 2–8°C prior to use:
- vii. Qiagen QIAmp DSP Viral RNA Mini Kit spin columns

- b. ThermoFisher MagMax Viral/Pathogen Nucleic Acid Isolation Kit using Altria's Kingfisher Flex Magnetic Particle Processor with 96 deep well head extraction platform.

The following reagents are stored at room temperature and expire per the manufacturer expiration date marked on the individual container.

- i. Binding Solution
- ii. Wash Buffer. Wash Solution may develop inert white or brown particulates that float in solution. This is not a cause for concern and does not negatively affect performance.

- iii. Elution Solution
- iv. Proteinase K
- v. Total Nucleic Acid Binding Beads
- vi. Ethanol, 100% (molecular biology grade)
- vii. Nuclease-free Water

- c. Perkin Elmer's Chemagic™ Viral DNA/RNA 300 Isolation Kit using Perkin Elmer Chemagic™360 Magnetic Bead extraction platform.
  - i. Poly(A) RNA; prepare according to manufacturer instructions; store in the dark; reconstituted Poly(A) is stable for 4 weeks at 4 °C; For long term storage store the reconstituted Poly(A) RNA in aliquots at -20 °C. Do not freeze the Poly(A) RNA aliquots after thawing.
  - ii. Proteinase K; prepare according to manufacturer instructions; reconstituted Proteinase K is stable for 4 weeks at 4 °C; For long term storage store the reconstituted Proteinase K in aliquots at -20 °C. Do not freeze the Proteinase K aliquots after thawing.

The follow reagents are stored at room temperature and expire per the kit expiration date:

- iii. Lysis Buffer 1; store in the dark; may form a precipitate upon storage. If necessary, warm to 55 °C to dissolve.
- iv. Binding Buffer 2
- v. Wash Buffers 3, 4 and 5
- vi. Elution Buffer 6
- vii. For long term storage it is recommended to store the reconstituted Poly(A) RNA and Proteinase K in aliquots at -20 °C. Do not freeze the Poly(A) RNA and Proteinase K aliquots after thawing.

- 2. PCR Set up and Detection; Prepare primers and probes per manufacturer instructions for use (CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel, Revision 05) :
  - a. 2019-nCoV\_N1 Combined Primer/Probe Mix
  - b. 2019-nCoV\_N2 Combined Primer/Probe Mix
  - c. Human RNase P Combined Primer/Probe Mix
  - d. 2019-nCoV Positive Control (nCoVPC)
    - i. Store all dried primers and probes and the positive control, nCoVPC, at 2-8°C until re-hydrated for use.
    - ii. Note: Storage information is for CDC primer and probe materials obtained through the International Reagent Resource.
    - iii. Protect fluorogenic probes from light.
    - iv. Primers, probes (including aliquots), and enzyme master mix must be thawed and kept on a cold block at all times during

preparation and use. **Consult most recent version of the package insert to confirm that dilution volumes have not changed.**

- v. Do not refreeze probes.
- vi. Controls and aliquots of controls must be thawed and kept on ice at all times during preparation and use.
- e. Human Specimen Control (HSC); Store liquid HSC control materials at  $\leq -20^{\circ}\text{C}$
- f. ThermoFisher TaqPath™ 1-Step RT-qPCR Master Mix, CG
  - i. Store Master Mix at  $-20 \pm 4^{\circ}\text{C}$ , follow manufacturer expiration date.
- g. Sterile, nuclease-free water (No Template Control)
  - i. Store at room temperature, follow manufacturer expiration date.

## VIII. PROCEDURE:

- A. Nucleic Acid Extraction: Perform one of the RNA extraction/purification procedures following the manufacturer's instructions for use with DCLS validated modification as specified:
1. Consult the FDA EUA website to confirm the most recent version of the IFU in use. <https://www.fda.gov/media/134922/download>
  2. Qiagen QIAamp® DSP Viral RNA Mini Kit or QIAamp® Viral RNA Mini Kit.
    - i. DCLS verified the performance of the both kits using 140-μL of sample and elution of viral RNA in 140-μL buffer.
  3. MagMax Viral/Pathogen Nucleic Acid Isolation Kit using ThermoFisher's KingFisher™ Flex Magnetic Particle Processor with 96 deep well head extraction platform (standard volume: 200–400 μL).
    - i. DCLS verified the use of the ThermoFisher KingFisher Flex using the automated program: "MVP\_Flex 96DW" Program on the KingFisher Flex.
    - ii. Procedure uses 400-μL patient sample
    - iii. Processing plates include an additional Wash 3 Plate (500-μL 80% Ethanol) (in reference to #MAN0019181 rev. H)
    - iv. Elution plate includes 100-μL Elution Solution
  4. Perkin Elmer's Chemagic™ Viral DNA/RNA 300 Isolation Kit using Perkin Elmer Chemagic™ 360 Magnetic Bead Extraction Platform; Purification Protocol for Viral DNA/RNA from 300 μl Plasma, Serum, Naso- or Oropharyngeal Swabs, BAL and Sputum Using the chemagic 360 with integrated chemagic Dispenser
    - i. DCLS verified the use of the **Perkin Elmer Chemagic 360** for the preparation of RNA with the Chemagic Viral DNA/RNA 300 Kit special

H96 using automated program: Chemagic Viral 300 360 H96 drying  
prefilling VD141210.che Program **on the Perkin Elmer Chemagic 360**

- ii. Sample input volume of 300-µL
- iii. Master Mix combined with respiratory specimen includes 300-µL Lysis Buffer, 4-µL Poly(A) RNA and 10-µL Proteinase K, once combined, samples are incubated 10 min
- iv. Processing plates include Low-Well Beads (150-µL), 3 Deep Well Washes
- v. Elution Plate includes 100-µL Elution buffer

- B. Perform PCR procedure using ThermoFisher TaqPath™ 1-Step RT-qPCR Master Mix per CDC; 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel.

#### **IX. CALCULATIONS:**

- A. Refer to manufacturer IFU's for any relevant calculation instructions.

#### **X. CALIBRATION, QUALITY CONTROL AND QUALITY ASSURANCE:**

- A. Refer to the manufacturer Instructions For Use, (CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel, Revision 05) for Quality Control for the SARS-CoV-2 assay.

- 1. A minimum of one set of positive and negative controls is processed on each PCR plate. Controls must yield the appropriate result to release results for patient samples.
  - a. No Template Control (NTC):
    - i. The NTC consists of using nuclease-free water in the rRT-PCR reactions instead of RNA.
    - ii. The NTC reactions for all primer and probe sets should not exhibit fluorescence growth curves that cross the threshold line. If any of the NTC reactions exhibit an amplification curve that crosses the cycle threshold, sample contamination may have occurred.
  - b. 2019-nCoV Positive Control (nCoVPC):
    - i. The nCoVPC consists of in vitro transcribed RNA.
    - ii. The nCoVPC will yield a positive result with the following primer and probe sets: N1, N2, and RP.
    - iii. A control preparation worksheet (Qualtrax ID #24640) is used to document the preparation of the positive PCR control.
  - c. Human Specimen Control (HSC) (Extraction Control):
    - i. HSC is used as a nucleic acid extraction procedural control to demonstrate successful recovery of nucleic acid as well as extraction reagent integrity. The HSC control consists of noninfectious cultured human cell material.
    - ii. HSC is extracted with each round of nucleic acid extraction



- and analyzed with concurrently extracted samples.
- iii. Purified nucleic acid from the HSC should yield a positive result with the RP primer and probe set and negative results with all 2019-nCoV markers.
- B. If any of the above controls do not exhibit the expected performance as described, the assay may have been set up and/or executed improperly, or reagent or equipment malfunction could have occurred. Invalidate the run and re-test.
- C. RNase P (Extraction Control):
1. All clinical samples should exhibit fluorescence growth curves in the RNase P reaction that cross the threshold line within 40.00 cycles (< 40.00 Ct), thus indicating the presence of the human RNase P gene.
  2. Failure to detect RNase P in any clinical specimens may indicate:
    - a. Improper extraction of nucleic acid from clinical materials resulting in loss of RNA and/or RNA degradation.
    - b. Absence of sufficient human cellular material due to poor collection or loss of specimen integrity.
    - c. Improper assay set up and execution.
    - d. Reagent or equipment malfunction.
    - e. If the RP assay does not produce a positive result for human clinical specimens, interpret as follows:
      - i. If the 2019-nCoV N1 and N2 are positive even in the absence of a positive RP, the result should be considered valid.
      - ii. If all 2019-nCoV markers AND RNase P are negative for the specimen, the result should be considered invalid for the specimen. If residual specimen is available, repeat the extraction procedure and repeat the test. If all markers remain negative after re-test, report the results as invalid and a new specimen should be collected if possible.

## **XI. WASTE MANAGEMENT**

*DCLS manages all waste streams in compliance with local, state, and federal regulations.*

- A. **Pollution Prevention**
1. *As part of DCLS' Pollution Prevention efforts, procedures are aimed at the elimination or reduction of hazardous waste discharge at the point of generation.*
  2. *Procedural decisions are based on the use of the least hazardous substance, limitations on the quantity ordered, the appropriate usage of the safety equipment, staff training, and competency assessment.*

3. *Training on waste management is provided to staff on an annual basis.*
- B. Biological, Chemical, Radiological Waste Handling
1. *The safety office provides assistance in the development of waste handling and storage procedures and coordinates hazardous waste pick-ups.*
  2. *A Waste Profile that is SOP-specific has been developed and approved. This information is listed on the DCLS Waste Profile Form (Qualtrax ID # 1646) which is attached to this SOP as Appendix 1.*
  3. *This method does not generate any hazardous radiological waste.*
  4. *This method generates the following hazardous chemical/biological (regulated medical waste)/radiological waste streams.*
    - a. Chemical
      - Expired unused extraction reagents including Buffer AVL (50%-100% guanidinium thiocyanate), Buffer AW1 (50-100% guanidine hydrochloride), and AW2 (50% ethanol)
      - Unused, unopened or expired hazardous kit components (including BTL, Viral/Pathogen Binding Solution, MagMax Viral Pathogen Proteinase K, BTL, Viral/Pathogen Wash Buffer, Ethanol, PerkinElmer Binding Buffer 2, PerkinElmer Wash Buffer 3, PerkinElmer Wash Buffer 4, PerkinElmer Lysis Buffer, PerkinElmer Proteinase K, PerkinElmer Poly(A) RNA Buffer)
      - 70% Cleaning Grade Ethanol (used for PerkinElmer Intensive Clean), PerkinElmer bulk reagent mixed waste (from Prime or Check Manifolds procedure. Contains PerkinElmer Binding Buffer 2, PerkinElmer Wash Buffer 3, PerkinElmer Wash Buffer 4, and PerkinElmer Wash Buffer 5.)
    - b. Biological ((regulated medical waste) if procedure generates biological waste or N/A):
      - *Gloves, disposable lab coats and other PPE should be disposed in the red regulated medical waste bins.*
      - Any waste that may have been in direct contact with samples
      - All testing materials used or generated in the BSC and items used during the processing of potentially infectious samples
      - All testing materials used or generated in Rooms 268A
      - Empty specimen containers and microcentrifuge tubes labeled with patient information

- c. Radiological: Not applicable

*Refer to the DCLS Safety Manual (Qualtrax ID # 1805) for Additional Safety information.*

C. Solid Waste

*Solid waste items that are associated with this procedure should be placed in trashcans for pick-up by BFM staff. The following items are considered solid waste: paper, paper towels, empty sample containers, food samples submitted for testing (that have tested negative) and the containers, expired media, non-infectious and non-chemical waste.*

D. On-Site Autoclave Preparation

*There are instances in which containers of potentially infectious materials may need to be autoclaved on site before being packaged for pick up by the regulated medical waste contractor or re-used in our laboratories.*

- BSL-3 Laboratories

*The following items are routinely packaged in this laboratory and placed in the pass-through autoclave in BSL-3.  
(All waste generated in BSL-3)*

*Refer to the DCLS Safety Manual (Qualtrax ID # 1805) or the BSL-3 Biosafety Manual (Qualtrax ID # 8650) for detailed instructions on how to properly prepare materials for autoclaving.*

## **XII. RECORDING AND REPORTING OF RESULTS:**

A. Record procedural steps completed on the applicable worksheet as follows:

1. 2019-nCoV Manual Extraction Worksheet (Qualtrax ID# 34067)
2. COVID-19 KingFisher Flex Extraction (Qualtrax ID# 33746)
3. Perkin Elmer Chemagic Viral DNA\_RNA 300 Extraction Worksheet (Qualtrax ID# 34019)
4. 2019-nCoV PCR Worksheet (Qualtrax ID# 33199)

B. Refer to the manufacturer Instructions For Use (IFU), (CDC; 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel, Revision 05) for Results for the SARS-CoV-2 assay. The table below lists the expected results for the 2019-nCoV rRT-PCR Diagnostic Panel.

2019 nCoV_N1	2019 nCoV_N2	RP	Result Interpretation <sup>a</sup>	Report	Actions
+	+	±	2019-nCoV detected	Positive 2019-nCoV	Report results to CDC and sender.
If only one of the two targets is positive		±	Inconclusive Result	Inconclusive	Repeat testing of nucleic acid and/or re-extract and repeat rRT-PCR. If the repeated result remains inconclusive, contact your State Public Health Laboratory or CDC for instructions for transfer of the specimen or further guidance.
-	-	+	2019-nCoV not detected	Not Detected	Report results to sender. Consider testing for other respiratory viruses. <sup>b</sup>
-	-	-	Invalid Result	Invalid	Repeat extraction and rRT-PCR. If the repeated result remains invalid, consider collecting a new specimen from the patient.

<sup>a</sup>Laboratories should report their diagnostic result as appropriate and in compliance with their specific reporting system.

<sup>b</sup>Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens from the same patient may be necessary to detect the virus. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation suggest that 2019-nCoV infection is possible, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If 2019-nCoV infection is still suspected, re-testing should be considered in consultation with public health authorities.

- C. Specimens that do not pass quality control requirements (unresolved) may include the following after comment on the patient report: Specimen did not pass quality control requirements, and collection of a new specimen for testing is recommended.
- D. Ensure that QC materials are verified and results are second reviewed and approved before releasing patient reports.
- E. Patient reports with CDC 2019-nCoV Assay results include the following disclaimer statements:
  - 1. The US Food and Drug Administration has made this test available under Emergency Use Authorization (EUA) for the duration of the COVID-19 declaration justifying emergency use of IVDs unless terminated or revoked. Results from this test should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19.
- F. Fact sheets on the CDC 2019-nCoV Test for healthcare providers and patients can be accessed at:
  - 1. <https://www.fda.gov/media/134920/download>
  - 2. <https://www.fda.gov/media/134921/download>

### **XIII. REFERENCES:**

1. CDC; 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel . Instructions for Use; CDC-006-00019; Revision 06; Effective 12/01/2020
2. CDC; 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel . Instructions for Use; CDC-006-00019; Revision 05; Effective 07/13/2020
3. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19); Updated Nov. 5, 2020; [https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fguidelines-clinical-specimens.html](https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fguidelines-clinical-specimens.html)
4. QIAamp DSP Viral RNA Mini Kit Handbook 03/2012
5. QIAamp Viral RNA Mini Handbook 07/2020
6. ThermoFisher/Applied Biosystems MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit (automated extraction) User Guide; Catalog Number A42352 Pub. No. MAN0018073 Rev. C.0; 24 September 2020
7. Purification Protocol for Viral DNA/RNA from 300 µl Plasma, Serum, Naso- or Oropharyngeal Swabs, BAL and Sputum Using the chemagic 360 with integrated chemagic Dispenser; Version 200312; 2018

### **XIV. APPENDIX, TABLES, DIAGRAMS, FLOWCHARTS AND VALIDATION DATA:**

Appendix I. Waste Profile Form

## Appendix I. DCLS Waste Profile

DCLS Waste Profile Form Richmond, VA		
Group: MDC	<input checked="" type="checkbox"/> New/Changed Waste Profile	
Contact: Sean Kelly ext 227		
SOP Name: CDC 2019-Novel Coronavirus Real Time RT-PCR Diagnostic Panel	SOP #:	
Waste Type (choose only one)	Waste Composition	
<input checked="" type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	Residual respiratory clinical specimens (nasopharyngeal (NP) swabs, oropharyngeal (OP) swabs, NP aspirates, NP wash, bronchoalveolar lavage, tracheal aspirates, sputum, etc.)
<input checked="" type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	Mixed waste containing carrier RNA, Buffer AVL (50-100% guanidine hydrochloride/ guanidinium thiocyanate), Buffer AW1 (50-100% guanidine hydrochloride), ethanol, Buffer AW2 (50% ethanol), residual clinical sample. Biological specimen waste from MagMax extractions (plastics and liquid waste used to extract biological specimens) including BTL, Viral/Pathogen Binding Solution, MagMax Viral Pathogen Proteinase K, BTL, Viral/Pathogen Wash Buffer, Ethanol, and other kit components of MagMax Viral/Pathogen kit. All plates removed from the PerkinElmer instrument following a run (plates contain Wash Buffer 3, Wash Buffer 4, Wash Buffer 5, Magnetic Beads, Lysis buffer, and inactivated sample).
<input checked="" type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	Mixed waste containing specimen, Sputolysin, and 10x TE
<input checked="" type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	Mixed waste containing filtrate of washing solution, sample retentate, bleach rite, etc.
<input checked="" type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	Used consumables: transfer pipets, serological pipettes, gloves, aerosol barrier tips, conicals, microcentrifuge tubes, forceps, elution columns, etc. generated during processing
<input checked="" type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	Cleaning supplies used during sample processing and cleaning BSC: bench coat, BleachRite, Microchem, Dispatch wipes, WypAlls, etc.
<input type="checkbox"/> Biological <input checked="" type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	<b>Unused expired reagents:</b> Buffer AVL (guanidinium thiocyanate), Buffer AW1 (50-100% guanidine hydrochloride), ethanol, Buffer AW2 (50% ethanol), 100% ethanol, PerkinElmer Binding Buffer 2, PerkinElmer Wash Buffer 3, PerkinElmer Wash Buffer 4, PerkinElmer Lysis Buffer, PerkinElmer Proteinase K, PerkinElmer Poly(A) RNA Buffer, BTL, Viral/Pathogen Binding Solution, MagMax Viral Pathogen Proteinase K, BTL, Viral/Pathogen Wash Buffer
<input checked="" type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	<b>Unused expired reagents:</b> carrier RNA, Buffer AVE, HSC, 10x Tris-EDTA (TE), Sputolysin (Sodium Citrate, Dithiothreitol), solid or liquid media, polyvalent
<input type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input checked="" type="checkbox"/> Sink <input type="checkbox"/> Trash	<b>Unused expired reagents:</b> Unused Tris-EDTA (TE) Buffer, unused PerkinElmer Wash Buffer 5, unused PerkinElmer Elution Buffer, unused PerkinElmer Magnetic Beads liquid (decant liquid when beads have settled)
<input checked="" type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	<b>BSL3 PPE:</b> Back closing gowns, gloves, N95 respirators, shoe covers.
<input type="checkbox"/> Biological <input checked="" type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	70% Cleaning Grade Ethanol (used for PerkinElmer Intensive Clean), PerkinElmer bulk reagent mixed waste (from Prime or Check Manifolds procedure. Contains PerkinElmer Binding Buffer 2, PerkinElmer Wash Buffer 3, PerkinElmer Wash Buffer 4, and PerkinElmer Wash Buffer 5.)
<input type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input checked="" type="checkbox"/> Trash	Unused PerkinElmer Magnetic Beads (after decanting liquid into the sink), unused lyophilized Poly(A) RNA
Comments:		
*Sink = non-hazardous aqueous solution or water soluble acid/base; Trash = solid waste		



**ThermoFisher TaqPath™ COVID-19 Combo Kit Procedure for the Detection of 2019-nCoV RNA by RT-PCR**

**I. PURPOSE/APPLICATION:**

- A. The purpose of this procedure is for the qualitative detection of nucleic acid from SARS-CoV-2 using real-time reverse transcription polymerase chain reaction (RT-PCR) amplification. Testing is performed for the purpose of patient diagnosis and surveillance of COVID-19 illness within Virginia at the direction of the Virginia Department of Health.
- B. The RT-PCR test is intended for the qualitative detection of nucleic acid from SARS-CoV2 in upper respiratory and bronchoalveolar lavage (BAL) specimens collected from individuals who meet clinical and/or epidemiological criteria. Testing in the United States is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests by trained laboratory personnel who are proficient in performing real-time RT-PCR assays. The TaqPath™ COVID-19 Combo Kit is only for use under a Food and Drug Administration Emergency Use Authorization (EUA).
- C. Deviations/modifications from the reference method validated and implemented by DCLS are listed in Section XIV, Table 1.

**II. SUMMARY/SCOPE:**

- A. The ThermoFisher TaqPath™ COVID-19 Combo Real-Time RT-PCR test is a molecular *in vitro* diagnostic test that aids in the qualitative detection of SARS-CoV-2 RNA in respiratory specimens and the diagnosis of COVID-19 illness. The test is based on widely used nucleic acid amplification technology. The product contains primers and probes specific to three SARS-CoV-2 genomic regions and primers/probes for bacteriophage MS2.
- B. The workflow begins with nucleic acid extraction from specimens in transport media. Nucleic acids are isolated and purified from specimens using the MagMax Viral/Pathogen Nucleic Acid Isolation Kit using the Kingfisher Flex Magnetic Particle Processor with 96 deep well head extraction platform or the Perkin Elmer's Chemagic™ Viral DNA/RNA 300 Isolation Kit using Perkin Elmer Chemagic™ 360 Magnetic Bead extraction platform. The nucleic acid is reverse transcribed into cDNA, and amplified using the TaqPath™ COVID-19 RT-PCR kit with the Applied Biosystems™ 7500 Fast Dx Real-Time PCR instrument. In the process, the probes anneal to three (3) specific SARS-CoV-2 target sequences located between three (3) unique forward and reverse primers for the following genes: ORF1ab, N Gene and S Gene. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. During each amplification cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle by the Applied Biosystems 7500 Fast Dx Real-Time PCR

instrument. The data are analyzed, then interpreted by the Applied Biosystems™ COVID-19 Interpretive Software. Detection of viral RNA not only aids in the diagnosis of illness but also provides epidemiological and surveillance information.

- C. Quality is assured through testing of positive and negative PCR controls with each run. A negative and a MS2 phage positive extraction control is included in each extraction run, and the purified nucleic acid traction run is included on each PCR run as an internal process control for nucleic acid extraction.
- D. DCLS validated two extraction methods for this procedure including:
  - 1. MagMax Viral/Pathogen Nucleic Acid Isolation Kit using the ThermoFisher Kingfisher Flex Magnetic Particle Processors with 96 deep well head extraction platform.
  - 2. Perkin Elmer's Chemagic™ Viral DNA/RNA 300 Isolation Kit using Perkin Elmer Chemagic™360 Magnetic Bead extraction platform.

### III. **SAMPLE COLLECTION:**

- A. Specimen Type:
  - 1. Sample types acceptable for testing per the IFU:
    - a. upper respiratory specimens for example:
      - i. nasopharyngeal or oropharyngeal swabs
      - ii. nasal and mid-turbinate swabs
      - iii. nasopharyngeal aspirate
    - b. respiratory specimens collected from individuals who meet 2019-nCoV clinical and/or epidemiological criteria. For example:
      - i. clinical signs and symptoms associated with 2019-nCoV infection
      - ii. contact with a probable or confirmed 2019-nCoV case
      - iii. history of travel to geographic locations where 2019-nCoV cases were detected
      - iv. other epidemiologic links for which 2019-nCoV testing may be indicated as part of a public health investigation.
  - 2. Swab specimens should be collected using only swabs with a synthetic tip, such as nylon or Dacron®, and an aluminum or plastic shaft. Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended.
  - 3. Place swabs immediately into sterile tubes containing 1-3 ml of appropriate transport media, such as viral transport media (VTM), Amies transport medium, phosphate buffered saline, or sterile saline.
- B. Handling and Shipping Conditions:
  - 1. Specimens can be stored at 2-8 °C for up to 72 hours after collection.
  - 2. Transport to DCLS refrigerated on ice packs.
  - 3. The DCLS COVID-19 Submission Form (Qualtrax ID # 34293) is the preferred form to submit specimens for testing. However, the DCLS Test Request Form (Qualtrax ID #16857) can also be used. **Specimens**

submitted using the DCLS SARS-CoV-2 Sequencing Submission Form (Qualtrax ID # 35889) may also require TaqPath COVID-19 PCR testing prior to initiating whole genome sequencing.

4. The DCLS Clinical Microbiology/Virology Request Form (Qualtrax ID # 16857) has been discontinued, but will be accepted if submitted with specimens.
5. The submission form should be fully completed by the submitter and submitted with the specimen; OR the submitter may use Webvision or DCLS Connect to electronically enter information for specimen submission. Information necessary for proper specimen submission:
  - a. Patient Information (name, address, age or date of birth)
  - b. Submitter Information (name, address, telephone number)
  - c. Patient Medical History (information relevant to diagnosis such as symptoms, date of onset, recent exposures, travel history)
  - d. Outbreak Information, if applicable, (outbreak number, role of patient in outbreak)
6. Test requested, specimen source, and date collected
7. When specimens are received in Sample Support Services (SSS), a LIMS identification number will be assigned. The patient information and specimen metadata will be entered into LIMS, labels will be generated and placed on the specimen container and appropriate paperwork. The specimens will be stored refrigerated in a SSS refrigerator until retrieved by testing personnel, or the specimens will be delivered to the COVID extraction laboratory (room 268A or B).

C. Storage Conditions:

1. When specimen is received at DCLS, store at 2-8 °C for up to 72 hours after collection.
2. If a delay in extraction is expected, store specimens at -70°C or lower.
3. Store extracted nucleic acid at -70°C or lower.
4. Maintain RNA on a cold block or on ice during preparation to ensure stability.
5. After testing is completed, specimens that are positive for SARS-CoV-2 by PCR will be aliquotted into cryovials and stored at -70°C or below for long term storage. Specimens that are negative for SARS-CoV-2 by PCR are discarded after testing is complete unless other reflex testing is required. Samples must be disposed of as biohazardous waste in a regulated medical waste bin.
6. Chain of Custody (COC) samples are discarded according to Evidence Receipt/Storage and Disposition Procedure (Qualtrax ID # 1804)

D. Rejection Criteria:

1. After consultation with the Senior Scientist, Principal Scientist, Lead Scientist, or Group Manager, samples meeting the rejection criteria outlined below may still be tested and reported with additional disclaimers.

- a. Absence of or inconsistent labeling and identification:
    - i. The absence of a name or unique identifier on specimen container.
    - ii. More than one name on specimen container.
    - iii. Name on paperwork is different from name on specimen container.
  - b. Specimen submission form not properly filled out (e.g. patient name or address missing, etc.).
  - c. Specimen received in expired viral transport medium.
  - d. Specimen received without refrigeration.
  - e. Specimen received at the laboratory more than 72 hours after collection date.
  - f. Specimen with insufficient volume for testing.
2. When a sample is deemed unacceptable for testing, the submitter will receive a LIMS report explaining the reason for specimen rejection (Unsatisfactory for testing - reason).

### 3. **PERSONNEL QUALIFICATIONS:**

*Procedures in Molecular Detection and Characterization Group (MDC) may only be performed by approved testing personnel. The list of testing personnel can be found in the DCLS Training Matrix. Testing personnel must comply with the (insert group specific competency plan if there is one) and DCLS Competency (Qualtrax ID # 16472). Personnel will demonstrate competency twice during the first year. Competency assessment, with documentation, will be performed annually in subsequent years.*

### 4. **INTERFERENCES/LIMITATIONS OF PROCEDURE:**

- A. This test has not been FDA cleared or approved; this test has been authorized by FDA under a EUA for use by laboratories certified under CLIA, 42 U.S.C. § 263a, to perform high complexity tests.
- B. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- C. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb3(b)(1), unless the authorization is terminated or revoked sooner.
- D. Amplification technologies such as PCR are sensitive to accidental introduction of PCR product from previous amplification reactions. Incorrect results could occur if either the clinical specimen or the real-time PCR reagents used in the amplification step become contaminated by accidental introduction of amplification product (amplicon). To mitigate this limitation, workflow in the laboratory proceeds in a unidirectional manner.
- E. Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false test results. Training in specimen collection is highly

- recommended due to the importance of specimen quality.
- F. Negative results do not preclude SARS-CoV2 infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by SARS-CoV2 have not been determined. Collection of multiple specimens (types and time points) from the same patient may be necessary to detect the virus.
  - G. The TaqPath™ COVID-19 RT-PCR Kit and the TaqPath™ COVID-19 RT-PCR Kit Advanced performance was established using nasopharyngeal and oropharyngeal swab, nasopharyngeal aspirate, and bronchoalveolar lavage samples only. Nasal swabs and mid-turbinate swabs are considered acceptable specimen types for use with the TaqPath™ COVID-19 RT-PCR Kit and the TaqPath™ COVID-19 RT-PCR Kit Advanced, but performance with these specimen types has not been established.
  - H. False-negative results may arise from improper sample collection, degradation of the SARS-CoV-2 RNA during shipping/storage, specimen collection after SARS-CoV-2 RNA can no longer be found in the specimen matrix, using unauthorized extraction or assay reagents, the presence of RT-PCR inhibitors, mutation in the SARS-CoV-2 virus, or failure to follow instructions for use.
  - I. False-positive results may arise from cross contamination during specimen handling or preparation, cross contamination between patient samples, specimen mix-up or RNA contamination during product handling.
  - J. Positive and negative predictive values are highly dependent on prevalence. False-negative test results are more likely when prevalence of disease is high. False-positive test results are more likely when prevalence is moderate to low.
  - K. Test performance can be affected because the epidemiology and clinical spectrum of infection caused by 2019-nCoV is not fully known. For example, clinicians and laboratories may not know the optimum types of specimens to collect, and, during the course of infection, when these specimens are most likely to contain levels of viral RNA that can be readily detected.
  - L. The impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated. The TaqPath™ COVID-19 RT-PCR Kit and the TaqPath™ COVID-19 RT-PCR Kit Advanced cannot rule out diseases caused by other bacterial or viral pathogens.
  - M. Limit of Detection of the the TaqPath™ COVID-19 Combo Kit is 10 GCE/reaction for BAL and Nasopharyngeal swab specimens.

## VI. SAFETY:

- A. Attire and Personal Protective Equipment
  1. *Totally enclosed shoes are required in this laboratory at all times.*
  2. *The required minimum Personal Protective Equipment (PPE) in this laboratory is a lab coat and safety glasses.*
  3. *Gloves are required when handling samples, infectious agents, chemicals,*

*closing and moving regulated medical waste containers, and when working in a biological safety cabinet (BSC) or chemical fume hood. Nitrile gloves are preferred.*

*NOTE: If latex gloves are in use, an alternative, non-latex glove must be available and laboratory door signage must reflect the usage of latex gloves.*

4. Additional PPE that should be used when performing nucleic acid extractions, instrument loading, specimen archiving in a Biosafety Level-2 (BSL-2) laboratory this procedure include:
    - fluid-impervious, back-closing gowns
    - double gloves when working in the BSC
    - face shields (if safety glasses fog due to face masks)
  5. Additional PPE that should be used when performing nucleic acid extractions of lower respiratory specimens in a Biosafety Level-3 (BSL-3) laboratory include:
    - respirators: PAPR or CAPR, N-95 with safety glasses
    - fluid-impervious, back-closing gowns
    - double gloves when working in the BSC
    - shoe covers
- B. *Safety precautions must be taken when handling reagents, samples, and equipment in this laboratory.*
- C. Special Precautions
1. BSL-2+ work practices will be used in BSL-2 testing laboratories.
  2. Lower respiratory specimens will be processed in a BSL-3 laboratory, using BSL-3 safety and work practices.
  3. Vortexing will occur inside of the BSC.
  4. Sealed rotors will be used for centrifugation steps, and will only be opened inside of a BSC.
  5. Vacuum manifolds will only be used inside of the BSC only.
  6. All items will be decontaminated prior to removal from the BSC
  7. Specimen containers are only opened inside of a BSC prior to inactivation via lysis buffer treatment for at least 10 minutes for the PerkinElmer Chemagic 360 extraction or 15 minutes for the KingFisher Flex extraction. Inactivated specimens may be removed from the BSC for loading onto the instrument.
  8. Closed specimen tubes can be handled on the benchtop for plate mapping preparations.
  9. Sharp items are discarded in sharps containers. Broken glass is discarded in a broken glass box and the box should not be filled more than 3/4 full. If broken glass has come in contact with a sample then it



is discarded in a sharps container. When ready to discard a sharps container, close the top securely and place it in a red regulated medical waste bin, or in the post lab, a designated cardboard box labeled with “regulated medical waste”.

D. Location of Eye Wash and Emergency Shower

1. *An eye wash/drench hose is present on each sink in this laboratory.*
2. *The emergency shower is located in room 250/IV and MDC/134.*

E. Hazards Associated With Procedure

1. Chemical Hazards

*The following toxic, carcinogenic, or highly hazardous,  $\leq 2$ , chemicals are associated with this procedure:*

Chemical Name	Health Hazards	Flam-mability	Reactivity	Oxidizing Solid/Liquid	Corrosive to Metals	Environ-mental Hazards	Fume Hood Required
Perkin Elmer Proteinase K*	1	N/A	N/A	N/A	N/A	N/A	No
BTL, Viral/Pathogen Binding Solution**	1	N/A	N/A	N/A	N/A	3	No
MagMAX Viral/Pathogen Proteinase K	1	N/A	N/A	N/A	N/A	N/A	No
BTL, Viral Pathogen Wash Buffer**	2	N/A	N/A	N/A	N/A	N/A	No
Ethanol***	2	2	N/A	N/A	N/A	N/A	No

\*Incompatible with Bleach

\*\*Incompatible with Acids and Bleach

\*\*\*Incompatible with strong oxidizing agents, strong acids, acid anhydrides, acid chlorides

2. Biological Hazards

- a. Respiratory viruses, including influenza, SARS-CoV-2, and other viruses, are human pathogens.
- b. All clinical specimens will be handled as potentially infectious materials using Universal Precautions as specified in the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030, [www.osha.gov](http://www.osha.gov)). Only personnel trained in handling infectious materials will be permitted to perform this procedure.
- c. Aerosol barrier pipette tips will be used to prevent the generation of aerosols. Wash hands thoroughly after handling specimens, reagents, and equipment, after removing gloves, and before leaving

the laboratory. Disinfect all bench tops and BSC after work is complete.

- d. Specimen coolers and packages containing COVID-19 specimens are opened on the benchtop by SSS staff. Samples are then placed inside of the BSC for accessioning. All sample tubes are decontaminated prior to removal from the BSC and delivery to the testing laboratory.

3. Radiological Hazards

*The following radiological hazards are associated with this procedure:  
Not Applicable.*

4. Safety Data Sheets/Pathogen Safety Data Sheets

*The laboratory is responsible for maintaining a current, complete file of Safety Data Sheets (SDSs) related to this procedure. The SDSs are available to the analyst on computers throughout the laboratory at the following URL: <https://msdsmanagement.msdsonline.com/21943a72-obc7-4000-a405-4ba03280a52c/ebinder/?nas=True>*

F. Spill Response

1. *Small spills - handled by the laboratory staff (refer to SDS) or call Administration for Spill Response Team notification.*
2. *Large spills – call Administration for Spill Response Team notification.*

*Refer to DCLS Safety Manual (Qualtrax ID # 1805) for additional safety information.*

**VII. EQUIPMENT & SUPPLIES, REAGENTS & STANDARDS:**

*For labeling requirements for purchased or prepared media/reagents/standards, refer to Measurement and Data Traceability (Qualtrax ID # 1789).*

- Equipment & Supplies: Store at room temperature unless otherwise specified
  1. Specimen Extraction
    - a. ThermoFisher Kingfisher Flex Magnetic Particle Processor with 96 deep well head extraction platform for use with MagMax Viral/Pathogen Nucleic Acid Isolation Kit.
      - i. KingFisher™ deep-well 96 plate
      - ii. KingFisher Duo cap for elution strip
      - iii. Adjustable micropipettors
      - iv. Multi-channel micropipettors
      - v. MicroAmp™ Clear Adhesive Film
      - vi. Conical Tubes (15 mL)

- vii. Conical Tubes (50 mL)
- viii. Reagent reservoirs
- ix. Nonstick, RNase-Free Microfuge Tubes, 1.5 mL
- x. Nonstick, RNase-Free Microfuge Tubes, 2.0 mL
- xi. Vortex
- xii. 96 deep-well magnetic head
- xiii. 96 deep-well heat block
- b. Perkin Elmer's Chemagic™ Viral DNA/RNA 300 Isolation Kit using Perkin Elmer Chemagic™360 Magnetic Bead extraction platform.
  - i. Rack with Disposable Tips
  - ii. low-well-plate (MICROTITER SYSTEM)
  - iii. Magnetic Beads
  - iv. deep-well-plate (riplate SW)

## 2. PCR Set up and Detection

- a. Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument (used with SDS Software v1.4.1)
- b. ABY™ Dye Spectral Calibration Plate for Multiplex qPCR, Fast 96-well (0.1-mL)
- c. JUN™ Dye Spectral Calibration Plate for Multiplex qPCR, Fast 96-well (0.1-mL)
- d. Vortex mixer
- e. Microcentrifuge
- f. Centrifuge, with a rotor that accommodates standard and deepwell microplates
- g. Single and multichannel adjustable pipettors (1 µL to 1,000.0 µL)
- h. Racks for 1.5 mL microcentrifuge tubes
- i. Cold block (96-well or 384-well) or ice
- j. Molecular grade water, nuclease-free
- k. 10% bleach (1:10 dilution of commercial 5.25-6.0% hypochlorite bleach)
- l. DNAPrep™ or equivalent
- m. RNase AWAY™ or equivalent
- n. Aerosol barrier pipette tips
- o. 1.5 mL microcentrifuge tubes (DNase/RNase free)
- p. 0.2 mL PCR reaction plates
- q. MicroAmp Optical 8-cap Strips
- r. MicroAmp™ Fast Optical 96-Well Reaction Plate with Barcode, 0.1 mL or a MicroAmp™ Optical 96-Well Reaction Plate with Barcode, 0.2 mL. Note: plates without a barcode can be used.
- s. MicroAmp™ Optical Adhesive Film
- t. Laboratory freezers –30°C to –10°C and ≤ –70°C

- Reagents:

- 1. Specimen Extraction; All solutions should be stored at room temperature (15–25°C) unless otherwise stated. Follow manufacturer

expiration dates.

- a. ThermoFisher MagMax Viral/Pathogen Nucleic Acid Isolation Kit using Altria's Kingfisher Flex Magnetic Particle Processor with 96 deep well head extraction platform.
  - i. Binding Solution
  - ii. Wash Buffer. Wash Solution may develop inert white or brown particulates that float in solution. This is not a cause for concern and does not negatively affect performance.
  - iii. Elution Solution
  - iv. Proteinase K
  - v. Total Nucleic Acid Binding Beads
  - vi. Ethanol, 100% (molecular biology grade)
  - vii. Nuclease-free Water
- b. Perkin Elmer's Chemagic™ Viral DNA/RNA 300 Isolation Kit using Perkin Elmer Chemagic™ 360 Magnetic Bead extraction platform.
  - i. Poly(A) RNA; prepare according to manufacturer instructions; store in the dark; reconstituted Poly(A) is stable for 4 weeks at 4 °C; For long term storage store the reconstituted Poly(A) RNA in aliquots at -20 °C. Do not freeze the Poly(A) RNA aliquots after thawing.
  - ii. Proteinase K; prepare according to manufacturer instructions; reconstituted Proteinase K is stable for 2 weeks at 4 °C; For long term storage store the reconstituted Proteinase K in aliquots at -20 °C. Do not freeze the Proteinase K aliquots after thawing.
  - iii. Lysis Buffer 1; store in the dark; may form a precipitate upon storage. If necessary, warm to 55 °C to dissolve.
  - iv. Binding Buffer 2
  - v. Wash Buffers 3, 4 and 5
  - vi. Elution Buffer 6
  - vii. For long term storage we recommend to store the reconstituted Poly(A) RNA and Proteinase K in aliquots at -20 °C. Do not freeze the Poly(A) RNA and Proteinase K aliquots after thawing.

2. PCR Set up and Detection; Prepare RT-PCR reagents per manufacturer Instructions For Use (TaqPath™ COVID-19 Combo Kit and TaqPath™ COVID-19 Combo Kit Advanced\* Instructions for Use) :  
TaqPath™ COVID-19 RT-PCR Kit; Store at –30°C to –10°C:
  - a. COVID-19 Real Time PCR Assay Multiplex (ORF1ab, N gene, S gene, MS2). Thaw on ice and refer to the COVID-19 TaqPath Combo Kit 400\_100 worksheet (Qualtrax ID # 34594)
  - b. MS2 Phage Control. Thaw on ice and use as is per the COVID 19 automated extraction worksheets (Qualtrax ID # 34648 and

- #34587).
- c. TaqPath™ COVID-19 Control (1 x 10<sup>4</sup> copies/μL); Store at ≤ –70°C. Refer to the COVID-19 TaqPath Combo Kit 400-100 worksheet (Qualtrax ID # 34594) for control preparation.
- d. TaqPath™ COVID-19 Control Dilution Buffer; Store at –30°C to –10°C
- e. Nuclease-free Water

## VIII. PROCEDURE:

- A. Nucleic Acid Extraction: Perform one of the RNA extraction/purification procedures following the manufacturer's instructions for use with DCLS validated modification as specified:
1. Consult the FDA EUA website to confirm the most recent version of the IFU in use (<https://www.fda.gov/media/136112/download>).
  2. MagMax Viral/Pathogen Nucleic Acid Isolation Kit using ThermoFisher's KingFisher™ Flex Magnetic Particle Processor with 96 deep well head extraction platform (standard volume: 200 – 400 μL).
    - a. DCLS verified the use of the ThermoFisher KingFisher Flex using the automated program: "MVP\_Flex 96DW" Program on the KingFisher Flex
    - b. Sample input volume of 400μL.
    - c. Extraction mixture combined with respiratory specimen includes 10μL Proteinase K and 550μL Binding Bead mixture. Once combined, samples are incubated 15 min prior to removal from the BSC.
    - d. 10 μL Phage Control used
    - e. Processing plates include an additional Wash 3 Plate (500μL 80% Ethanol) (in reference to #MAN0019181 rev. H)
    - f. Elution plate includes 100μL Elution Solution
  3. Perkin Elmer's Chemagic™ Viral DNA/RNA 300 Isolation Kit using Perkin Elmer Chemagic™ 360 Magnetic Bead Extraction Platform; Purification Protocol for Viral DNA/RNA from 300 μl Plasma, Serum, Naso- or Oropharyngeal Swabs, BAL and Sputum Using the chemagic 360 with integrated chemagic Dispenser
    - a. DCLS verified the use of the **Perkin Elmer Chemagic 360** for the preparation of RNA with the Chemagic Viral DNA/RNA 300 Kit special H96 using automated program: Chemagic Viral 300 360 H96 drying prefilling VD141210.che Program **on the Perkin Elmer Chemagic 360**
    - b. Sample input volume of 300μL
    - c. Master Mix combined with respiratory specimen includes 300μL Lysis Buffer, 4μL Poly(A) RNA and 10μL Proteinase K, once combined, samples are incubated 10 min prior to removal from

- the BSC.
    - d. 7.5 µL Phage Control used
    - e. Processing plates include Low-Well Beads (150µL), 3 Deep Well Washes
    - f. Elution Plate includes 100µL Elution buffer
- B. Perform PCR procedure using TaqPath™ COVID-19 Combo Kit and TaqPath™ COVID-19 Combo Kit Advanced\* Instructions for Use with DCLS validated modification as specified. Refer to the following sections:
  - 1. Prepare the RT-PCR reactions (Refer to pages 34-36 of IFU, sections 4-5, for RNA preparation and reaction plate set-up)
    - a. PCR reaction mixture (per sample) includes:
      - 6.25µL TaqPath 1-Step Multiplex Master Mix (No ROX, 4X)
      - 1.25µL COVID-19 Real-Time PCR Assay Multiplex
      - 7.5µL Nuclease-free water
    - b. 10µL purified sample RNA used as template
    - c. 10µL purified Negative Control (from RNA extraction) used for Negative Control reaction
    - d. 2-µL Positive Control (diluted TaqPath COVID-19 control) + 8 uL nuclease-free water used as Positive Control reaction
    - e. 10-µL nuclease-free water used as the Non-Template Control (NTC)
  - 2. Set up and run the 7500 Fast Dx Real-Time PCR Instrument using the “TaqPath COVID-19 Kit” ABI template (refer to COVID-19 TaqPath Combo Kit 400\_100 worksheet (Qualtrax ID #34594))
  - 3. Analysis and results procedure:
    - a. Interpretation of the results is performed by the Applied Biosystems™ COVID-19 Interpretive Software. For information about the Ct values that are used by the software to interpret results, refer to the Instructions for Use for “Ct cutoff values for assay targets”.
    - b. DCLS **does not** utilize the TaqMan SARS-CoV-2 RNase P assay; therefore, the COVID-19 Interpretive Software is used for data analysis and interpretation for patient reports.
    - c. For detailed instructions about using the software, refer to AB COVID-19 Interpretive Software Job Aid (Qualtrax ID# 34604).
    - d. For troubleshooting purposes only, refer to AB Design & Analysis Software Job Aid (Qualtrax ID# 34605).

## IX. CALCULATIONS:

- A. Refer to manufacturer IFU's for any relevant calculation instructions.

## **X. CALIBRATION, QUALITY CONTROL AND QUALITY ASSURANCE:**

- A. Refer to the manufacturer Instructions For Use, (TaqPath™ COVID-19 Combo Kit and TaqPath™ COVID-19 Combo Kit Advanced) for Quality Control for the SARS-CoV-2 assay.
1. For each RT-PCR reaction plate, include the following controls:
    - a. One Positive Control
    - b. One Negative Control from each extraction run. For example, if RNA samples from 4 extraction runs are combined on one 384-well RT-PCR reaction plate, then 4 Negative Control wells must be run on that 384-well reaction plate.
  2. If any of the above controls do not exhibit the expected results as described, the assay may have been set up and/or executed improperly, or reagent or equipment malfunction could have occurred. Invalidate the run and re-test.
  3. All control wells must pass for the real-time RT-PCR plate to be considered valid. Validation of results is performed automatically by the Applied Biosystems™ COVID-19 Interpretive Software based on performance of the Positive and Negative Controls.
  4. Verify the performance of all testing reagents with control materials prior to releasing patient results.

## **XI. WASTE MANAGEMENT**

*DCLS manages all waste streams in compliance with local, state, and federal regulations.*

- A. Pollution Prevention
1. *As part of DCLS' Pollution Prevention efforts, procedures are aimed at the elimination or reduction of hazardous waste discharge at the point of generation.*
  2. *Procedural decisions are based on the use of the least hazardous substance, limitations on the quantity ordered, the appropriate usage of the safety equipment, staff training, and competency assessment.*
  3. *Training on waste management is provided to staff on an annual basis.*
- B. Biological, Chemical, Radiological Waste Handling
1. *The safety office provides assistance in the development of waste handling*



*and storage procedures and coordinates hazardous waste pick-ups.*

2. *A Waste Profile that is SOP-specific has been developed and approved. This information is listed on the DCLS Waste Profile Form (Qualtrax ID # 1646) which is attached to this SOP as Appendix I.*
3. *This method does not generate any hazardous radiological waste.*
4. *This method generates the following hazardous chemical/biological (regulated medical waste)/radiological waste streams.*
  - a. **Chemical**
    - Expired, unused extraction reagents, including Buffer AVL (50%-100% guanidinium thiocyanate), Buffer AW1 (50-100% guanidine hydrochloride), and AW2 (50% ethanol)
    - Mixed waste containing Buffer AVL (50%-100% guanidinium thiocyanate), Buffer AW1 (50%-100% guanidine hydrochloride), 100% ethanol, Buffer AW2 (50% ethanol), viral transport media.
  - b. **Biological (regulated medical waste):**
    - *Gloves, disposable lab coats and other PPE should be disposed in the red regulated medical waste bins.*
    - Any waste that may have been in direct contact with samples
    - All testing materials used or generated in the BSC and items used during the processing of potentially infectious samples
    - Empty specimen containers and microcentrifuge tubes labeled with patient information
  - c. **Radiological: Not applicable**

*Refer to the DCLS Safety Manual (Qualtrax ID # 1805) for Additional Safety information.*

**C. Solid Waste**

*Solid waste items that are associated with this procedure should be placed in trashcans for pick-up by BFM staff. The following items are considered solid waste: paper, paper towels, empty sample containers, food samples submitted for testing (that have tested negative) and the containers, expired media, non-infectious and non-chemical waste.*

**D. On-Site Autoclave Preparation**

*There are instances in which containers of potentially infectious materials may need to be autoclaved on site before being packaged for pick up by the regulated*

*medical waste contractor or re-used in our laboratories.*

1. BSL-3 Laboratories

*The following items are routinely packaged in this laboratory and placed in the pass-through autoclave in BSL-3.*

All waste generated in BSL-3.

*Refer to the DCLS Safety Manual (Qualtrax ID # 1805) or the BSL-3 Biosafety Manual (Qualtrax ID # 8650) for detailed instructions on how to properly prepare materials for autoclaving.*

**XII. RECORDING AND REPORTING OF RESULTS:**

- A. Record procedural steps completed on the applicable worksheet as follows:
  - 1. MS2 KF Flex Extraction (Qualtrax ID # 34587)
  - 2. MS2 PE chemagic Viral DNA\_RNA 300 Extraction Worksheet (Qualtrax ID # 34648)
  - 3. COVID-19 TaqPath Combo Kit 400\_100 (Qualtrax ID # 34594)
- B. Refer to the manufacturer Instructions For Use (IFU), (TaqPath™ COVID-19 Combo Kit and TaqPath™ COVID-19 Combo Kit Advanced) for Results for the SARS-CoV-2 assay. The table below lists the expected patient results for the TaqPath™ COVID-19 Combo Kit.

ORF1ab	N gene	S gene	MS2	Status	Result	Action
NEG	NEG	NEG	NEG	INVALID	NA	Repeat test by re-extracting the original sample and repeating the RT-PCR. If the repeat result remains invalid, consider collecting a new specimen.
Any result				INVALID	NA	The patient sample may be invalid because the same sample name (Sample ID) was assigned to multiple wells in the instrument software.  In the Samples pane of the Home screen, review all samples with a status of <b>INVALID</b> . If there are duplicate sample names: In the instrument software, correct the sample names, for EDS files change the experiment name, save the file with a new file name, then import the corrected file into the interpretive software.
NEG	NEG	NEG	POS	VALID	SARS-CoV-2 Not Detected	Report results to the healthcare provider and appropriate public health authorities. Consider testing for other viruses.
Only one SARS-CoV-2 target = POS			POS or NEG	VALID	SARS-CoV-2 Inconclusive <sup>(1)</sup>	<ol style="list-style-type: none"> <li>1. Repeat test by re-extracting the original sample and repeating the RT-PCR.</li> <li>2. After retesting one time, report results to the healthcare provider and appropriate public health authorities.</li> </ol> <p><b>IMPORTANT!</b> Samples with a result of SARS-CoV-2 Inconclusive shall be retested one time.</p> <p>If the repeat result remains inconclusive, the healthcare provider should conduct additional confirmation testing with a new specimen, if clinically indicated.</p>
Two or more SARS-CoV-2 targets = POS			POS or NEG	VALID	Positive SARS-CoV-2	Report results to the healthcare provider and appropriate public health authorities.

<sup>(1)</sup> Samples with a result of SARS-CoV-2 Inconclusive shall be retested one time.

- A. Ensure that QC materials are verified and results are second reviewed and approved before being released on patient reports.
1. Import data to PCR COVID-19 Multi Results Cover Sheet (Qualtrax ID # 35047) and submit to reviewer.

B. Disclaimers and After Comments:

1. **Patient reports with TaqPath COVID-19 Combo Kit assay results** include the following disclaimer statements:

- i. *PCR COVID-19 Multi Disclaimer: The US Food and Drug Administration has made this test available under emergency use authorization (EUA) for the duration of the COVID-19 declaration justifying emergency use of IVDs unless terminated or revoked. Results from this test should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19.*

*Fact sheets on the TaqPath COVID-19 Combo kit for healthcare providers and patients can be accessed at <https://www.fda.gov/media/136111/download>, or <https://www.fda.gov/media/136114/download>.*

2. If the initial result for a specimen is **inconclusive or invalid**, reflex testing may be performed using any COVID-19 test currently validated at DCLS.

- i. If initial testing is performed using the TaqPath COVID-19 Combo assay and repeat testing is performed using a different assay, apply the following after comment to the TaqPath COVID-19 Combo Assay step conclusion:

**REPEAT TESTING WILL BE PERFORMED. PLEASE REFER TO ADDITIONAL RESULTS FOR FINAL TEST REPORTING.**

- ii. If initial testing and repeat testing are both performed using the TaqPath COVID-19 Combo assay and the test result remains inconclusive or invalid, apply the following after comment to the TaqPath COVID-19 Combo assay step conclusion:

**REPEAT TESTING WAS PERFORMED. THIS IS A FINAL TEST RESULT.**

**XIII. REFERENCES:**

1. TaqPath™ COVID-19 Combo Kit and TaqPath™ COVID-19 Combo Kit Advanced\* Instructions for Use; Publication Number MAN0019181
2. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19); Updated Nov. 5, 2020; <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical->

[specimens.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fguidelines-clinical-specimens.html](https://www.cdc.gov/coronavirus/2019-ncov/guidelines-clinical-specimens.html)

3. ThermoFisher/ appliedbiosystems MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit (automated extraction) User Guide; Catalog Number A42352 Pub. No. MAN0018073 Rev. C.0; 24 September 2020
4. Purification Protocol for Viral DNA/RNA from 300 µl Plasma, Serum, Naso- or Oropharyngeal Swabs, BAL and Sputum Using the chemagic 360 with integrated chemagic Dispenser; Version 200312; 2018

#### **XIV. APPENDIX, TABLES, DIAGRAMS, FLOWCHARTS AND VALIDATION DATA:**

##### **Appendix I. Waste Profile Form**

## Appendix I. DCLS Waste Profile

DCLS Waste Profile Form Richmond, VA		
Group: MDC	<input checked="" type="checkbox"/> New/Changed Waste Profile	
Contact: Sean Kelly ext 227		
SOP Name: ThermoFisher TaqPath COVID-19 Real Time PCR Assay	SOP #: 36677	
Waste Type (choose only one)	Waste Composition	
<input checked="" type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	Residual respiratory clinical specimens (nasopharyngeal (NP) swabs, oropharyngeal (OP) swabs
<input checked="" type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	Biological specimen waste from MagMax extractions (plastics and liquid waste used to extract biological specimens) including BTL, Viral/Pathogen Binding Solution, MagMax Viral Pathogen Proteinase K, BTL, Viral/Pathogen Wash Buffer, Ethanol, and other kit components of MagMax Viral/Pathogen kit. All plates removed from the PerkinElmer instrument following a run (plates contain Wash Buffer 3, Wash Buffer 4, Wash Buffer 5, Magnetic Beads, Lysis buffer, and inactivated sample).
<input checked="" type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	Used consumables: transfer pipets, serological pipettes, gloves, aerosol barrier tips, conicals, microcentrifuge tubes, forceps, elution columns, etc. generated during processing
<input checked="" type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	Cleaning supplies used during sample processing and cleaning BSC: bench coat, BleachRite, Microchem, Dispatch wipes, WypAlls, etc.
<input type="checkbox"/> Biological <input checked="" type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	<b>Unused expired reagents:</b> PerkinElmer Binding Buffer 2, PerkinElmer Wash Buffer 3, PerkinElmer Wash Buffer 4, PerkinElmer Lysis Buffer, PerkinElmer Proteinase K, PerkinElmer Poly(A) RNA Buffer, BTL, Viral/Pathogen Binding Solution, MagMax Viral Pathogen Proteinase K, BTL, Viral/Pathogen Wash Buffer
<input checked="" type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	<b>Unused expired reagents:</b> HSC, solid or liquid media, polyvalent
<input type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input checked="" type="checkbox"/> Sink <input type="checkbox"/> Trash	<b>Unused expired reagents:</b> Unused Tris-EDTA (TE) Buffer, unused PerkinElmer Wash Buffer 5, unused PerkinElmer Elution Buffer, unused PerkinElmer Magnetic Beads liquid (decant liquid when beads have settled)
<input checked="" type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	<b>PPE:</b> Back closing gowns, gloves, N95 respirators, shoe covers.
<input type="checkbox"/> Biological <input checked="" type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input type="checkbox"/> Trash	70% Cleaning Grade Ethanol (used for PerkinElmer Intensive Clean), PerkinElmer bulk reagent mixed waste (from Prime or Check Manifolds procedure. Contains PerkinElmer Binding Buffer 2, PerkinElmer Wash Buffer 3, PerkinElmer Wash Buffer 4, and PerkinElmer Wash Buffer 5.)
<input type="checkbox"/> Biological <input type="checkbox"/> Chemical <input type="checkbox"/> Radiological	<input type="checkbox"/> Sink <input checked="" type="checkbox"/> Trash	Unused PerkinElmer Magnetic Beads (after decanting liquid into the sink), unused lyophilized Poly(A) RNA
Comments:		
*Sink = non-hazardous aqueous solution or water soluble acid/base; Trash = solid waste		

Commonwealth of Virginia  
Department of General Services  
Division of Consolidated Laboratory Services  
Richmond, Virginia

**ThermoFisher TaqPath™ COVID-19 Combo Kit Procedure for the Detection of 2019-nCoV RNA by RTPCR**  
**Table 1: DCLS modifications to the ThermoFisher TaqPath™ COVID-19 Combo Kit Procedure for the Detection of 2019-nCoV RNA\***

Procedural Step:	Reference Method and Detail:	Does SOP reflect reference method?	List modification in DCLS Validated Method:	Does modification change chemistry of procedure and/or is modification specifically prohibited by reference method?	List explanation/justification for modifications that change the chemistry of the procedure and/or are specifically prohibited in the reference method:
TaqPath COVID-19 Combo Kit IFU #MAN0019181 rev. G, pg. 14: Instrument, assay and software compatibility	<ul style="list-style-type: none"> <li>Per IFU, the 7500 Fast-Dx Real-Time PCR Instrument with the SDS Analysis Software v1.4.1 data may be analyzed at a minimum with COVID-19 Interpretive Software version 1.3 if the test procedure <b>does not</b> include the TaqMan SARS-Cov-2 RNase P Assay, or with COVID-19 Interpretive Software version 1.4 if the test procedure <b>does</b></li> </ul>	Yes	<ul style="list-style-type: none"> <li>DCLS <b>does not</b> utilize the TaqMan SARS-CoV-2 RNase P assay; therefore, the COVID-19 Interpretive Software version 1.3 is used for data analysis and interpretation for patient reports</li> </ul>	No	<ul style="list-style-type: none"> <li>COVID-19 Interpretive Software version 1.3 was verified by DCLS for data analysis, interpretation and reporting.</li> </ul>



	include the TaqMan SARS-Cov-2 RNase P Assay				
TaqPath COVID-19 Combo Kit IFU #MAN0019181 rev. G, pg. 24: KingFisher Flex MagMax Viral/Pathogen Nucleic Acid Isolation Kit: Extract RNA – Automated Method (400-µL sample input volume)	<ul style="list-style-type: none"> <li>Automated Program: “MVP_2Wash_4 00” Flex Program from the MagMAX Viral/Pathogen II Nucleic Acid Isolation Kit product page <b>on the KingFisher Flex</b></li> <li>Processing plates include Wash 1 Plate (1000-µL Wash Solution) and Wash 2 Plate (1000-µL 80% Ethanol)</li> <li>Elution Plate includes 50-µL Elution Solution</li> </ul>	No	<ul style="list-style-type: none"> <li>Automated Program: “<b>MVP_Flex 96DW</b>” Program <b>on the KingFisher Flex</b></li> <li>Processing plates include an additional Wash 3 Plate (500-µL 80% Ethanol)</li> <li>Elution plate includes 100-µL Elution Solution</li> </ul>	Yes	<ul style="list-style-type: none"> <li>The processing protocol was used for the validation study.</li> <li>The second 80% Ethanol wash (Wash 3 plate) is performed per the manufacturer product insert for the MagMax Viral/Pathogen Nucleic Acid Isolation Kit (MAN0018073, Rev. C.0), and was used for the validation study.</li> <li>The elution volume was used for the validation study to provide additional extraction material for repeat testing and additional characterization, this elution volume is within the range specified in the manufacturer product insert for the MagMax Viral/Pathogen Nucleic Acid Isolation Kit (MAN0018073, Rev. C.0).</li> </ul>
TaqPath COVID-19 Combo Kit IFU #MAN0019181 rev. G, pg. 24: KingFisher Flex MagMax	<ul style="list-style-type: none"> <li>Automated Program: MVP_2Wash_40 0 Flex Program from the MagMAX Viral/Pathogen II</li> </ul>	No	<ul style="list-style-type: none"> <li>DCLS additionally verified the use of the <b>Perkin Elmer Chemagic 360</b> for the preparation of</li> </ul>	Yes	<ul style="list-style-type: none"> <li>Manufacturer representatives programed the extraction protocol used for SARS-CoV-2 RNA on the Chemagic 360, <b>Chemagic Viral300 360 H96 drying prefilling VD141210.che</b>, upon instrument installation at DCLS in April 2020, this protocol was used in</li> </ul>

Viral/Pathogen Nucleic Acid Isolation Kit: Extract RNA – Automated Method (400- µL sample input volume)	Nucleic Acid Isolation Kit product page <ul style="list-style-type: none"> <li>• Sample input volume of 400-µL</li> <li>• 10-µL Proteinase K added to each sample well, followed by 550-µL Binding Bead Mix</li> <li>• 10-µL MS2 Phage Control Used</li> <li>• Processing plates include Wash 1 Plate (1000-µL Wash Solution) and Wash 2 Plate (1000-µL 80% Ethanol)</li> <li>• Elution Plate includes 50-µL Elution Solution</li> </ul>		RNA with the Chemagic Viral DNA/RNA 300 Kit special H96 (Reference: PerkinElmer Purification Protocol for Viral DNA/RNA from 300-µL Plasma, Serum, Naso- or Oropharyngeal Swabs, BAL and Sputum using the Chemagic 360 with Integrated Chemagic Dispenser, Version 200312) <ul style="list-style-type: none"> <li>• Automated extraction program: <b>Chemagic Viral300 360 H96 drying prefilling VD141210.che</b> Program on the <b>Perkin Elmer Chemagic 360</b></li> <li>• Sample input</li> </ul>		the validation. <ul style="list-style-type: none"> <li>• The processing protocol with the <b>Perkin Elmer Chemagic 360</b> was adopted due to lack of access to automated instrumentation and reagents and supplies in the pandemic. The <b>Perkin Elmer Chemagic 360</b> processing protocol with the Chemagic Viral DNA/RNA 300 Kit special H96 was validated for use with the <b>TaqPath COVID-19 Combo Kit</b>.</li> <li>• The amount of phage control used was adjusted to maintain the ratio of phage to sample in the IFU #MAN0019181 rev. G assay.</li> <li>• The elution volume was standardized to obtain the same eluate across the KingFisher Flex and Perkin Elmer platforms for the TaqPath PCR assay, this elution volume is within the range specified in the manufacturer product insert for the purification of Viral DNA/RNA from specimens using the Chemaic 360 (Version 200312).</li> </ul>
---	--	--	--	--	---

			<p>volume of 300-<math>\mu</math>L</p> <ul style="list-style-type: none"> <li>• Master Mix combined with respiratory specimen includes 300-<math>\mu</math>L Lysis Buffer, 4-<math>\mu</math>L Poly(A) RNA and 10-<math>\mu</math>L Proteinase K, once combined, samples are incubated 10 min prior to removal from the BSC</li> <li>• 7.5-<math>\mu</math>L Phage Control Used</li> <li>• Processing plates include Low-Well Beads (150-<math>\mu</math>L), 3 Deep Well Wash</li> <li>• Elution Plate includes 100-<math>\mu</math>L Elution buffer</li> </ul>		
<p>TaqPath COVID-19 Combo Kit IFU #MAN0019181 rev. G, pg. 38: Prepare the</p>	<ul style="list-style-type: none"> <li>• PCR reaction mixture (per sample) includes: <ul style="list-style-type: none"> <li>○ 6.25-<math>\mu</math>L TaqPath 1-</li> </ul> </li> </ul>	No	<ul style="list-style-type: none"> <li>• PCR reaction mixture (per sample) includes: <ul style="list-style-type: none"> <li>○ 6.25-<math>\mu</math>L TaqPath 1-</li> </ul> </li> </ul>	Yes	<ul style="list-style-type: none"> <li>• The amount of Sample RNA, Positive Control and Negative Control added were used in the DCLS validation study.</li> <li>• The amount of template and control materials added maintains the same ratio of nucleic acid to reaction mixture</li> </ul>

RT-PCR reactions (400 µL sample input, 960-well reaction plate, COVID-19 assay only)	<p>Step Multiplex Master Mix (No ROX) (4X)</p> <ul style="list-style-type: none"> <li>○ 1.25-µL COVID-19 Real-Time PCR Assay Multiplex</li> <li>○ 12.5-µL Nuclease-free water</li> <li>• 5-µL purified sample RNA used as template</li> <li>• 5-µL purified Negative Control (from RNA extraction) used for Negative Control reaction</li> <li>• 2-µL Positive Control (diluted TaqPath COVID-19 control) + 3 uL nuclease-free water used as Positive Control reaction</li> </ul>		<p>Step Multiplex Master Mix (No ROX) (4X)</p> <ul style="list-style-type: none"> <li>○ 1.25-µL COVID-19 Real-Time PCR Assay Multiplex</li> <li>○ 7.5-µL Nuclease-free water</li> <li>• 10-µL purified sample RNA used as template</li> <li>• 10-µL purified Negative Control (from RNA extraction) used for Negative Control reaction</li> <li>• 2-µL Positive Control (diluted TaqPath COVID-19 control) + 8 uL nuclease-free water used as Positive Control reaction</li> </ul>		<p>used in the “200-µL sample input PCR reactions” described on page 34 of #MAN0019181.</p> <ul style="list-style-type: none"> <li>• The template amount used reflects the same input volume and elution volume ratios for the DCLS validated method (400-µL sample input, 100-µL elution) and the “200-µL sample input” Automated Method (200-µL sample input, 50-µL elution) on Pg. 21 of #MAN0019181 rev. G</li> <li>• DCLS added a PCR NTC to detect cross-contamination on the PCR plate</li> </ul>
--	---	--	--	--	--

			<ul style="list-style-type: none"> <li>10-μL nuclease-free water used as the Non-Template Control (NTC)</li> </ul>		
--	--	--	--	--	--

\*Qualifying External Components statement from CDC EUA procedure: "If a laboratory modifies this test by using unauthorized, alternative components (e.g., extraction methods or PCR instruments), the modified test is not authorized under this EUA. FDA's Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency, updated May 11, 2020, does not change this. As part of this policy, FDA does not intend to object when a laboratory modifies an EUA-authorized test, which could include using unauthorized components, without 10 CDC-006-00019, Revision: 05 CDC/DDID/NCIRD/ Division of Viral Diseases Effective: 07/13/2020 obtaining an EUA or EUA amendment, where the modified test is validated using a bridging study to the EUA-authorized test."

**Subject: Access to Info Request: records re PURIFICATION OF “SARS-COV-2”**

**August 11<sup>th</sup> 2021**

**To: Phillip Husband Esq.  
DC Health  
899 North Capitol Street, NE, 6th Floor  
Washington, DC 20002  
Phillip.Husband@dc.gov  
Phone: (202) 442-5977  
Fax: (202) 442-4797**

**Dear Mr. Husband,**

This is a formal request for access to general records, made under Maryland's Public Information Act.

**Description of Requested Records:**

All studies and/or reports in the possession, custody or control of the DC Health Department of Health (MDH) describing the **purification** of any **“COVID-19 virus”** (aka “SARS-COV-2”, including any alleged “variants” i.e. “B.1.1.7”, “B.1.351”, “P.1”) directly from a sample taken from a diseased human, where the patient sample was not first combined with any other source of **genetic** material (i.e. monkey kidney cells aka Vero cells; fetal bovine serum).

Please note that I am not requesting studies/reports where researchers failed to **purify** the suspected “virus” (separate the alleged “virus” from everything thing else in the patient sample) and instead:

- cultured an unpurified sample or other unpurified substance, and/or
- performed an amplification test (i.e. a PCR test) on the total RNA from a patient sample or from a cell culture, or on genetic material from any unpurified substance, and/or
- fabricated a genome based on PCR-detected sequences in the total RNA from a patient sample or from a cell culture or from any unpurified substance, and/or
- produced electron microscopy images of unpurified things in a cell culture.

## Clarification of Request

For further clarity, please note I am already aware that according to virus theory a “virus” requires host cells in order to replicate, and I am **not** requesting records describing the **replication** of a “virus” without host cells.

Further, I am **not** requesting records that describe a suspected “virus” floating in a vacuum; I am simply requesting records that describe its **purification (separation)** from everything else in the patient sample, as per standard laboratory practices for the purification of other very small things).

Please note that my request includes any study/report matching the above description, for example (but not limited to) any published peer-reviewed study **authored by anyone, anywhere**.

Please also note that despite the fact that [purification is an essential](#) (but not sufficient) step in proving the existence of a disease-causing “virus”, as of today [68 institutions globally](#) (including the U.S. CDC, Public Health Agency of Canada, Australian Department of Health, New Zealand Ministry of Health, European Centre for Disease Prevention and Control, UK Department for Health and Social Care, Indian Council of Medical Research) have all failed to provide or cite any such records, therefore to my knowledge no such records exist and if they do exist I cannot access them until I am provided a citation or URL.

Therefore in the interest of transparency and in accordance with the purposes of the legislation (Open Government and FOIA - DC Health), if any records match the above description of requested records and are currently available to the public elsewhere, please provide enough information about each record so that I may identify and access each one with certainty (i.e. title, author(s), date, journal, where the public may access it). Please provide URLs where possible.

### Format:

Pdf documents sent to me via email; I do not wish for anything to be shipped to me.

### Contact Information:

Last name: [REDACTED]

First name: [REDACTED]

Address: [REDACTED]

Phone: [REDACTED]

Email: [REDACTED]





Office of the General Counsel

August 13, 2021

Via email: [REDACTED]

[REDACTED]

Re: Freedom of Information Act Request  
Subject: Purification of COVID-19  
2021-FOIA-07248

Dear [REDACTED]

Your Freedom of Information Act (FOIA) request seeks “studies and/or reports ... describing the **purification** of any “**COVID-19 virus**” (aka “SARS-COV-2”, including alleged variants ....”  
[Bolding in original]

**FOIA Response**

The Government of the District of Columbia has posted COVID-19 documents, data, and information on <https://coronavirus.dc.gov/>.

When I conferred with the Director of the Department of Health regarding your FOIA request, I was advised that the Department of Health has not been involved in any research or day-to-day activities related to purification of SARS-CoV-2. No letters, reports, or documents (other than your FOIA request) regarding a purification process have been received by the Director of the Department of Health.

**Referrals to Other Agencies**

The separate Office of the Chief Medical Officer (OCME) and the Public Health Laboratory operated by the separate Department of Forensic Sciences (DFS) may have documents responsive to your FOIA request. If you have not done so already, you may wish to submit FOIA request to OCME and DFS. The contact information for OCME's FOIA Officer and DFS' FOIA Officer is:

Rodney Adams  
FOIA Officer  
Office of the Chief Medical Examiner

401 E Street, S.W.  
Washington, DC 20024  
Email: [rodney.adams@dc.gov](mailto:rodney.adams@dc.gov)  
Phone: (202) 698-9005  
Fax: (202) 698-9101

Andrea Stempel  
FOIA Officers  
Department of Forensic Sciences  
401 E Street, SW, Fourth Floor  
Washington, DC 20024  
Phone: (202) 442-6673  
Email: [DFS.FOIA@dc.gov](mailto:DFS.FOIA@dc.gov)

### **Final Response**

This letter constitutes my final response on behalf of the Department of Health to your FOIA request.

### **FOIA Fees**

FOIA fees for this response have been waived.

### **Appeal Rights**

Please know that, under D.C. Official Code § 2-537 and 1 DCMR § 412, you have the right to appeal this letter to the Mayor or to the Superior Court of the District of Columbia. Your appeal must be in writing or submitted via FOIAXpress.

Please know that, under D.C. Official Code § 2-537 and 1 DCMR § 412, you have the right to appeal this response to the Mayor or to the Superior Court of the District of Columbia. If you elect to appeal to the Mayor, your appeal must be in writing and contain "Freedom of Information Act Appeal" or "FOIA Appeal" in the subject line of the letter as well on the outside of the envelope. The appeal must include (1) a copy of the original request; (2) a copy of any written denial; (3) a statement of the circumstances, reasons, and/or arguments advanced in support of disclosure; and (4) a daytime telephone number, an email address, and U.S. Mail address at which you can be reached. The appeal must be mailed to: The Mayor's Office of Legal Counsel, FOIA Appeal, 1350 Pennsylvania Avenue, N.W., Suite 407, Washington, D.C. 20004. Electronic versions of the same information can instead be emailed to [foia.appeals@dc.gov](mailto:foia.appeals@dc.gov). Further, a copy of all appeal materials must be forwarded to Phillip L. Husband, Freedom of Information Act Officer for the Department of Health, Office of the General Counsel, Department of Health, 899 North Capitol Street, N.E., 6<sup>th</sup> Floor, Washington, DC 20002 or via email to [Phillip.Husband@dc.gov](mailto:Phillip.Husband@dc.gov). Failure to follow these administrative steps will result in delay in the processing and commencement of a response to your appeal to the Mayor.

If you used FOIAXpress to submit your FOIA request, you may create an appeal by using FOIAXpress.

Failure to follow these administrative steps will result in delay in the processing and commencement of a response to your appeal to the Mayor.

If I may be of further assistance, please call me at (202) 442-5970 or e-mail me at [Phillip.Husband@dc.gov](mailto:Phillip.Husband@dc.gov).

Sincerely,

A handwritten signature in blue ink, appearing to read "Phillip L. Husband", is written over a horizontal line.

Phillip L. Husband  
General Counsel for the Department of Health  
and Freedom of Information Act Officer



Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30333

October 26, 2021

***SENT VIA EMAIL***

[REDACTED]

[REDACTED]

This letter is our final response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of September 20, 2021, assigned #21-02310-FOIA, for

This is a formal request for access to general records, made under the *Freedom of Information Act*.

**Please note:** this request is very similar to another request CDC/ATSDR responded to in March, 2021 where I had **specified** purification *via maceration, filtration and use of an ultracentrifuge*.

The difference with this new request is that it does **not specify** maceration, filtration and use of an ultracentrifuge; it only mentions filtration, ultracentrifugation and chromatography by way of an example.

My request also includes the language of 'variants' to ensure that records would match all related alleged SARS-COV-2 viruses.

**Description of Requested Records:**

All studies and/or reports in the possession, custody or control of Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) describing the **purification** of any **“COVID-19 virus” (aka “SARS-COV-2”, including any alleged “variants” i.e. “B.1.1.7”, “B.1.351”, “P.1”)** (for example: via filtration, ultracentrifugation and chromatography), directly from a sample taken from a diseased human where the patient sample was not first combined with any other source of **genetic** material (i.e. monkey kidney cells aka Vero cells; fetal bovine serum).

Please note that I am not requesting studies/reports where researchers failed to **purify** the suspected "virus" and instead:

- cultured an unpurified sample or other unpurified substance, and/or
- performed an amplification test (i.e. a PCR test) on all the RNA from a patient sample or from a cell culture, or on genetic material from any unpurified substance, and/or
- fabricated a "genome" by editing/assembling/aligning sequences detected in the total RNA from a patient sample or from a cell culture or from any unpurified substance, and/or
- produced electron microscopy images of unpurified things.

For further clarity, please note I am already aware that according to virus theory a "virus" requires host cells in order to replicate, and I am **not** requesting records describing the **replication** of a "virus" without host cells.



Further, I am **not** requesting records that describe a suspected "virus" floating in a vacuum; I am simply requesting records that describe its **purification (separation)** from everything else in the patient sample, as per standard laboratory practices for the purification of other very small things).

Please also note that my request is **not limited** to records that were authored by CDC/ATSDR or that pertain to work done at/by CDC/ATSDR. Rather, my request includes any record matching the above description, for example (but not limited to): any published peer-reviewed study authored by anyone, anywhere, ever that has been downloaded or printed by CDC/ATSDR and relied on as evidence of a disease-causing "virus".

If any records match the above description of requested records and are currently available to the public elsewhere, please provide enough information about each record so that I may identify and access each one with certainty (i.e. title the public may access it).

Please provide URLs where possible.

For administrative convenience and to fully respond to your request, program staff have provided the following information below with corresponding web links.

SARS-CoV-2 is the virus that causes coronavirus disease 2019 (COVID-19). Active infection with SARS-CoV-2 is detected by [diagnostic tests](#). Currently there are two types of diagnostic tests – molecular tests that detect the virus's genetic material and antigen tests that detect specific proteins on the surface of the virus. For current data showing the total number of SARS-CoV-2-positive cases and deaths, visit the [CDC COVID-19 Data Tracker](#), which shows cases and deaths in the United States broken down by state and county, daily trends in the number of cases by state, and other parameters.

Evidence of SARS-CoV-2 infection can be found in a study entitled, [Pathology and Pathogenesis of SARS-CoV-2 Associated with Fatal Coronavirus Disease](#), which includes electron microscopy images of SARS-CoV-2 in infected lung and upper airway tissues as well as staining of lung and upper airway tissues using an antibody against SARS-CoV-2.

The specimens analyzed in this study were from patients with common signs and symptoms associated with COVID-19, including fever, cough, and shortness of breath. All patients had abnormal findings on chest radiographs.

There are other similar studies publicly available online. To aid in locating other related studies, please see the articles suggested in the "Similar Articles" and "Cited by" section on the manuscript's [PubMed entry](#).

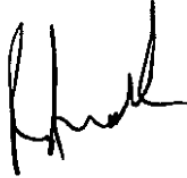
The SARS-CoV-2 virus, whether the original strain or variants of the virus, may be isolated from human clinical specimens by culturing in cells. In January 2020, CDC [isolated the SARS-CoV-2 virus](#) from a clinical specimen from the first confirmed case of COVID-19 in the United States. There are other similar studies published describing the isolation and characterization of SARS-CoV-2 from human clinical specimens. To aid in locating other related studies, please see the articles suggested in the "Similar Articles" and "Cited by" section on the manuscript's [PubMed entry](#). There are also [several publications](#) documenting SARS-CoV-2 infection and transmission among pre-symptomatic and asymptomatic individuals.

For information about the SARS-CoV-2 genome sequence, see the NIH GenBank website (<https://www.ncbi.nlm.nih.gov/genbank/sars-cov-2-seqs/>), which includes over 1 million sequences.

For more information about specific variants, searches can be performed on PubMed and other databases. Additionally, users can filter millions of genomic sequences by variant on genomic sequence databases like GISAID (<https://www.gisaid.org/hcov19-variants/>) and GenBank ([https://www.ncbi.nlm.nih.gov/labs/virus/vssi/#/virus?SeqType\\_s=Nucleotide&VirusLineage\\_ss=SARS-CoV-2,%20taxid:2697049](https://www.ncbi.nlm.nih.gov/labs/virus/vssi/#/virus?SeqType_s=Nucleotide&VirusLineage_ss=SARS-CoV-2,%20taxid:2697049)).

If you need any further assistance or would like to discuss any aspect of the records provided please contact either our FOIA Requester Service Center at 770-488-6399 or our FOIA Public Liaison at 770-488-6277.

Sincerely,

A handwritten signature in black ink, appearing to read 'Roger Andoh', with a stylized, cursive script.

Roger Andoh  
CDC/ATSDR FOIA Officer  
Office of the Chief Operating Officer  
Phone: (770) 488-6399  
Fax: (404) 235-1852



## FOI re: SARS-COV-2 & Variants purification by any method

3 messages

Sun, Oct 10, 2021 at 7:55 AM

To: ems@clemson.edu

Dear Public Information Officer William Shivar,

This is a formal request for access to general records, made under the *Freedom of Information Act*.

### Description of Requested Records:

All studies and/or reports in the possession, custody or control of Clemson University describing the **purification** of any "COVID-19 virus" (aka "SARS-COV-2", including any alleged "variants" i.e. "B.1.1.7", "B.1.351", "P.1") (for example: via filtration, ultracentrifugation and chromatography), directly from a sample taken from a diseased human where the patient sample was not first combined with any other source of **genetic** material (i.e. monkey kidney cells aka Vero cells; fetal bovine serum).

Please note that I am not requesting studies/reports where researchers failed to **purify** the suspected "virus" and instead:

- cultured an unpurified sample or other unpurified substance, and/or
- performed an amplification test (i.e. a PCR test) on all the RNA from a patient sample or from a cell culture, or on genetic material from any unpurified substance, and/or
- fabricated a "genome" by editing/assembling/aligning sequences detected in the total RNA from a patient sample or from a cell culture or from any unpurified substance, and/or
- produced electron microscopy images of unpurified things.

For further clarity, please note I am already aware that according to virus theory a "virus" requires host cells in order to replicate, and I am **not** requesting records describing the **replication** of a "virus" without host cells.

Further, I am **not** requesting records that describe a suspected "virus" floating in a vacuum; I am simply requesting records that describe its **purification** (**separation** from everything else in the patient sample, as per standard laboratory practices for the purification of other very small things).

Please also note that my request is **not limited** to records that were authored by Clemson University or that pertain to work done at/by Clemson University. Rather, my request includes any record matching the above description, for example (but not limited to): any published peer-reviewed study authored by anyone, anywhere, ever that has been downloaded or printed by Clemson University and relied on as evidence of a disease-causing "virus".

Please note, I am requesting all records regardless if the records are publicly available or privately available.

If any records match the above description of requested records and are currently available to the public elsewhere, please provide enough information about each record so that I may identify and access each one with certainty (i.e. title, author(s), date, journal, where the public may access it). Please provide URLs where possible.

### Format:

Pdf documents sent to me via email; I do not wish for anything to be shipped to me.

### Record Search

I do not expect the University to search students' computers, labs' computers, or even researchers' computers. I expect the University to direct this request to the appropriate department who have *experts* in the field of virology & microbiology such as the Department of Environmental Engineering and Earth Sciences who recently received [\\$900K to study SARS-COV-2](#).

### Complexity

Please Note, this is not a complex request nor is it a request that will generate too many records to search through. I have already done a preliminary record search through Google Scholar and have read many scientific papers on this subject. I have not found any responsive publicly and privately available scientific records including records referenced and published by the USA CDC.

Regards

---

Robert Wilkins <bertw@clemson.edu>

Sat, Oct 23, 2021 at 5:43 AM

Cc: Amy McKinney Josey <amjosey@clemson.edu>

Good afternoon 

I hope you are doing well. Your FOIA request below was forwarded to me for response. I have directed your below request to the appropriate departments. The University does not have records responsive to your request.



I hope you have a nice weekend.

Best regards,

***Robert W. Wilkins***

***Assistant General Counsel***

***Clemson University***

***207 Sikes Hall***

***Clemson, SC 29634***

**864.656.3414**

**[bertw@clemson.edu](mailto:bertw@clemson.edu)**

Begin forwarded message:

[REDACTED]  
**Date:** October 9, 2021 at 14:56:01 EDT  
**To:** William Shivar <[ems@clemson.edu](mailto:ems@clemson.edu)>  
**Subject:** FOI re: SARS-COV-2 & Variants purification by any method  
[REDACTED]

[Quoted text hidden]

# OFFICE OF THE GOVERNOR

207 STATE HOUSE  
SPRINGFIELD, ILLINOIS 62706

**JB PRITZKER**  
GOVERNOR

October 15, 2021

**VIA EMAIL**

[michelleturney1771@att.net](mailto:michelleturney1771@att.net)

Re: FOIA Request # 2021-268

Dear Ms. Turney:

This letter is in response to your narrowed Illinois Freedom of Information Act ("FOIA") request received on October 7, 2021 seeking:

All records of scientific laboratory studies analyzing and identifying the SARS-CoV-2 virus from an isolated sample extracted from a human being. am unable to find proof of the above.

Please be advised that after conducting a search, the Governor's Office has located no records responsive to your request.

To the extent you consider this response to be a denial of your FOIA request, you have the right to a denial reviewed by the Office of the Illinois Attorney General, 500 S. 2nd Street, Springfield, Illinois 62706, (877) 299-3642, [publicaccess@atg.state.il.us](mailto:publicaccess@atg.state.il.us).

If you choose to submit a request for review, you must do so within 60 days after the date of this response letter. The request for review must be in writing, signed by you, and include a copy of your FOIA request and this office's response. 5 ILCS 140/9.5(a). In addition, you have the right to seek judicial review of this response. 5 ILCS 140/11(a), (b).

If you have any questions or need additional information, please contact me.

Sincerely,



Shannon I. Leonard, FOIA Officer  
Office of Illinois Governor JB Pritzker

Tony Evers  
Governor



Karen E. Timberlake  
Secretary

**State of Wisconsin**  
Department of Health Services

**OFFICE OF LEGAL COUNSEL**

1 WEST WILSON STREET  
PO BOX 7850  
MADISON WI 53707-7850

Telephone: 608-266-8428  
Fax: 608-267-1434  
TTY: 711 or 800-947-3529

September 24, 2021

Charles Haeuser

Racine, WI

Email: cchaeuser@gmail.com

RE: Your August 14, 2021 Public Records Requests

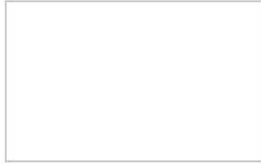
Dear Mr. Haeuser:

This is in response to your public records requests received by the Department of Health Services on August 14, 2021. You requested:

- All studies and/or reports in the possession, custody or control of the State of Wisconsin, Department of Health Services, Governor of the State of Wisconsin, Any contracted employees or Laboratories contracted by The State of Wisconsin, Department of Health Services or its duly appointed entities describing the purification (i.e. via filtration and ultracentrifugation) of any "COVID-19 virus" (aka "SARS-COV-2", including any alleged "variants" i.e. "B.1.1.7", "B.1.351", "P.1") directly from a sample taken from a diseased human, where the patient sample was not first combined with any other source of genetic material (i.e. monkey kidney cells aka Vero cells; fetal bovine serum).
- [A]ny/all internal documents that refer to, or indicate who authorized the total amount and any and all records regarding research done into the use of the word vaccine, the safety of any vaccine and any records that the Department of Health Services has that show an approval of any "vaccine or inoculation" that was approved by the FDA for safe, ethical use on anyone, anywhere.
- The NAME, JOB TITLE/DESCRIPTION of all persons employed by the Wisconsin Department of Health Services, OR other State of Wisconsin agencies or employees and ANY/ALL elected officials involved in the "COVID-19 Community Outreach Grant" Process.
- [A] copy of the application for Racine County and Vaccinate Racine! Listed on page 3 of the document P-02953 (04/2021) Posted by the Department of Health Services website. To include any correspondence or relevant documents, emailed, faxed, or otherwise in relation to this application and it's approval by The Department of Health Services for a "COVID-19 Community Outreach Grant". When was the Grant approved for \$100,000.00 and who approved it. Who was paid the Grant money.

10/20/21, 5:19 PM

Gmail - FW: Open Records Requests



---

**From:** [Chuck H](#)  
**Sent:** Monday, September 27, 2021 7:31 PM  
**To:** [REDACTED]  
**Subject:** FW: Open Records Requests

I think it's safe to say that Wisconsin is UP ShIT cREEK

Sent from [Mail](#) for Windows

---

**From:** [Hunnicut, Stephanie L - DHS](#)  
**Sent:** Friday, September 24, 2021 1:37 PM  
**To:** [cchaeuser@gmail.com](mailto:cchaeuser@gmail.com)  
**Subject:** Open Records Requests

Dear Mr. Haeuser,

Please see the attached response to your open records requests.

Thank you,


---

*Stephanie Hunnicutt*

Paralegal  
DHS/Office of Legal Counsel

1 W WILSON ST RM 651  
PO BOX 7850  
MADISON WI 53707-7850









☎ Direct Line: (608) 267-4029  
☎ Fax: (608) 267-1434

 DHS Logo - Color with Text

**NOTICE of PRIVILEGED and CONFIDENTIAL COMMUNICATION:** This email and any attachments may contain confidential information or information protected by the attorney-client privilege. Use and further disclosure of the information by the recipient must be consistent with applicable laws, regulations, or agreements. If you received this email in error, please notify the sender; delete the email; and do not use, disclose, or store the information it contains.

---

**8 attachments**

-  **1 - Converted To PDF\_Redacted.pdf**  
10136K
-  **2 - COVID-19 Vaccination Outreach RFA - Review Manual (final) (3).pdf**  
412K
-  **3 - COVID19\_Vaccine\_Community\_Outreach\_Awardees\_033021.xlsx**  
61K
-  **4 - RFA Reviewer Scores All-Discussion.xlsx**  
288K
-  **5 - X\_COVID-19 Vaccination Outreach RFA - Reviewer 12 - Score Sheet.xlsx**  
44K
-  **6 - X\_COVID-19 Vaccination Outreach RFA - Reviewer 19 - Score Sheet.xlsx**  
55K
-  **7 - X\_COVID-19 Vaccination Outreach RFA - Reviewer 20 Score Sheet.xlsx**  
51K
-  **Response Letter.pdf**  
243K

Tony Evers  
Governor



**OFFICE OF LEGAL COUNSEL**

1 WEST WILSON STREET  
PO BOX 7850  
MADISON WI 53707-7850

Karen E. Timberlake  
Secretary

**State of Wisconsin**  
**Department of Health Services**

Telephone: 608-266-8428  
Fax: 608-267-1434  
TTY: 711 or 800-947-3529

September 24, 2021

Charles Haeuser  
3543 River Bend Drive  
Racine, WI 53404  
Email: cchaeuser@gmail.com

RE: Your August 14, 2021 Public Records Requests

Dear Mr. Haeuser:

This is in response to your public records requests received by the Department of Health Services on August 14, 2021. You requested:

- All studies and/or reports in the possession, custody or control of the State of Wisconsin, Department of Health Services, Governor of the State of Wisconsin, Any contracted employees or Laboratories contracted by The State of Wisconsin, Department of Health Services or its duly appointed entities describing the purification (i.e. via filtration and ultracentrifugation) of any "COVID-19 virus" (aka "SARS-COV-2", including any alleged "variants" i.e. "B.1.1.7", "B.1.351", "P.1") directly from a sample taken from a diseased human, where the patient sample was not first combined with any other source of genetic material (i.e. monkey kidney cells aka Vero cells; fetal bovine serum).
- [A]ny/all internal documents that refer to, or indicate who authorized the total amount and any and all records regarding research done into the use of the word vaccine, the safety of any vaccine and any records that the Department of Health Services has that show an approval of any "vaccine or inoculation" that was approved by the FDA for safe, ethical use on anyone, anywhere.
- The NAME, JOB TITLE/DESCRIPTION of all persons employed by the Wisconsin Department of Health Services, OR other State of Wisconsin agencies or employees and ANY/ALL elected officials involved in the "COVID-19 Community Outreach Grant" Process.
- [A] copy of the application for Racine County and Vaccinate Racine! Listed on page 3 of the document P-02953 (04/2021) Posted by the Department of Health Services website. To include any correspondence or relevant documents, emailed, faxed, or otherwise in relation to this application and it's approval by The Department of Health Services for a "COVID-19 Community Outreach Grant". When was the Grant approved for \$100,000.00 and who approved it. Who was paid the Grant money.

- Please include all relevant dates as they pertain to ANY INFORMATION IN THIS REQUEST.  
The NAME, JOB TITLE/DESCRIPTION of all persons who approved this amount of money for this purpose at the Department of Health Services, and where did the money come from.  
The NAME, JOB TITLE/DESCRIPTION of all persons who approved this amount of money for this purpose elected or employed by the State of Wisconsin, and where did the money come from.

DHS has no responsive records to the first two bullets of your request. It should also be noted that DHS does not conduct any of its own studies on COVID-19 samples and nor does DHS conduct its own vaccine safety and effectiveness research. That research is part of the process of vaccine approval overseen the U.S. Food and Drug Administration (“FDA”), and DHS relies on the direction and guidance of the FDA and the U.S. Centers for Disease Control and Prevention (“CDC”) with respect to vaccine safety, including which vaccines are approved for a specified use. For more information on COVID-19 diagnostics, you might consider visiting: <https://www.cdc.gov/amd/index.html>.

The records responsive to your request regarding the Community Outreach Grants and specifically Racine county’s application and award are enclosed. Pursuant to the common law balancing test and consistent with Wis. Stat. § 995.50, we made efforts to redact the cell phone number of a local government partner. Making this information available could subject these partners to harassing contact and would constitute an invasion of their privacy. The public’s interest in individual privacy outweighs any minimal harm, especially given that no other identifying information has been withheld. The strong public interest in knowing who is contacting the Department or other government partners is not affected by withholding this individual’s cell phone number.

We also redacted links to video conference calls. Making those available would cause unnecessary and unwarranted interruptions for employees and could allow unauthorized access to discussions potentially involving confidential information. Pursuant to the common law balancing test, we have concluded that the public interest in efficient state business functions outweighs any minimal public interest in access to that information.

If you believe that we have improperly determined that the information should not be provided to you, you have a right under Wis. Stat. § 19.37 to have the determination reviewed by *mandamus* or upon application to the attorney general or district attorney. If you have any questions, please do not hesitate to contact me at [DHSOpenRecords@dhs.wisconsin.gov](mailto:DHSOpenRecords@dhs.wisconsin.gov).

Sincerely,

***Stephanie Hunnicutt***

Stephanie Hunnicutt  
Paralegal