



sanofi pasteur

The vaccines division of sanofi-aventis Group

Product Quality and Disposition Department

Diphtheria, tetanus, pertussis (acellular, component),
hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus
influenzae type b conjugate vaccine (adsorbed) lot n° S4312 (clinical batch) 143/229

MONOVALENT BULK - Type : 1
Lot Number : FA303359

Single harvest used : FA295889 – FA297421
Date of inactivation : 17.03.08
Inactivation method : 0.88% (w/v) Formaldehyde, 37°C, 12 days

Date of manufacture : 17.03.08
Volume : 260 550 ml
Storage temperature : +5°C ± 3°C
Monovalent bulk period of validity : 3 years
Expiry date : 17 MARCH 2011

CONTROLS:

Residual formaldehyde content

Method : Spectrophotometry
Date : 25.03.08
Result : 84.62 µg/ml - **Conforms**

Protein content

Method : Spectrophotometry
Date : 26.03.08
Result : 21.83 µg/ml

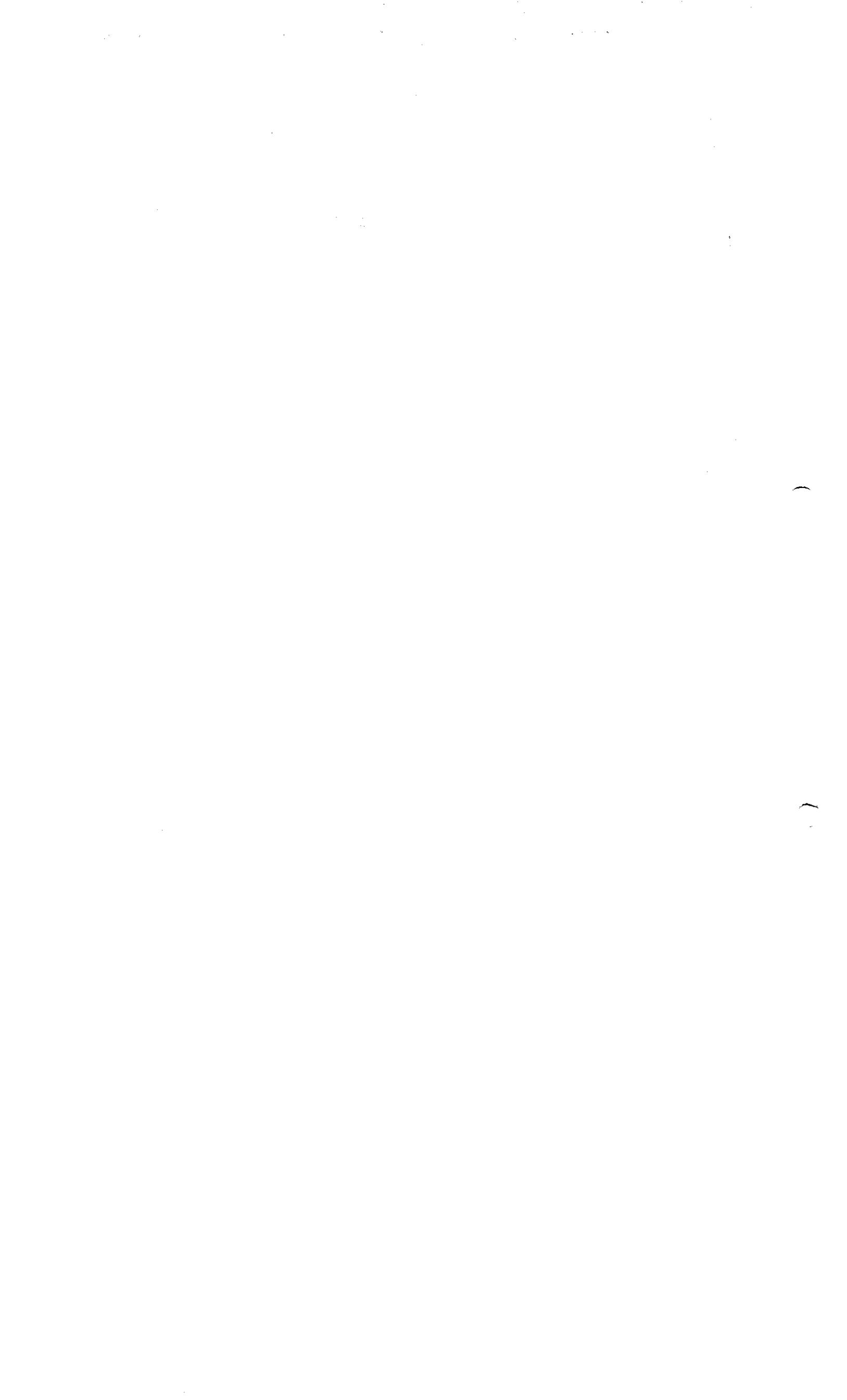
D Antigen content

Method : ELISA
Reference standard : 28.1.99
Date : 25.03.08
Result : 1 218 D Antigen U/ml

Purity

Result : 17.922 ng of protein / D Antigen U - **Conforms**

[Handwritten signatures]
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CHRISTIAN DOMINGUEZ JEFE DE AREA SANOFI PASTEUR S.A.





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Bacterial and fungal sterility



Method used	:	Membrane filtration	
Media	:	Thioglycollate medium	Soybean Casein Digest medium
Temperatures	:	30-35° C	20-25° C
Volume tested	:	20 ml	
Inoculum per Steritest	:	10 ml	10 ml
Volume of medium per Steritest	:	100 ml	100 ml
Test on	:	19.03.08	
Test off	:	02.04.08	
Result	:	No microbial growth	

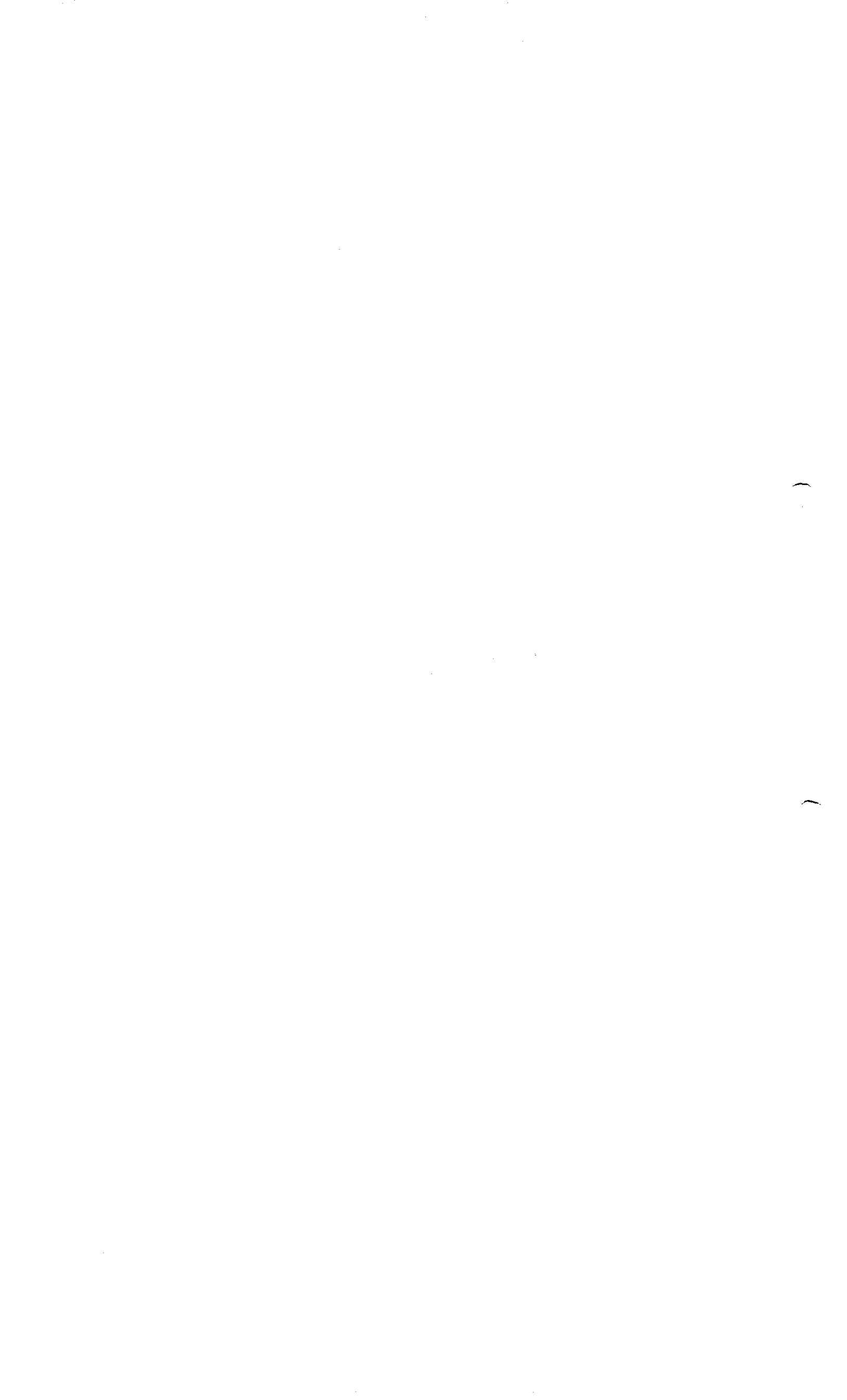
Inactivation kinetics

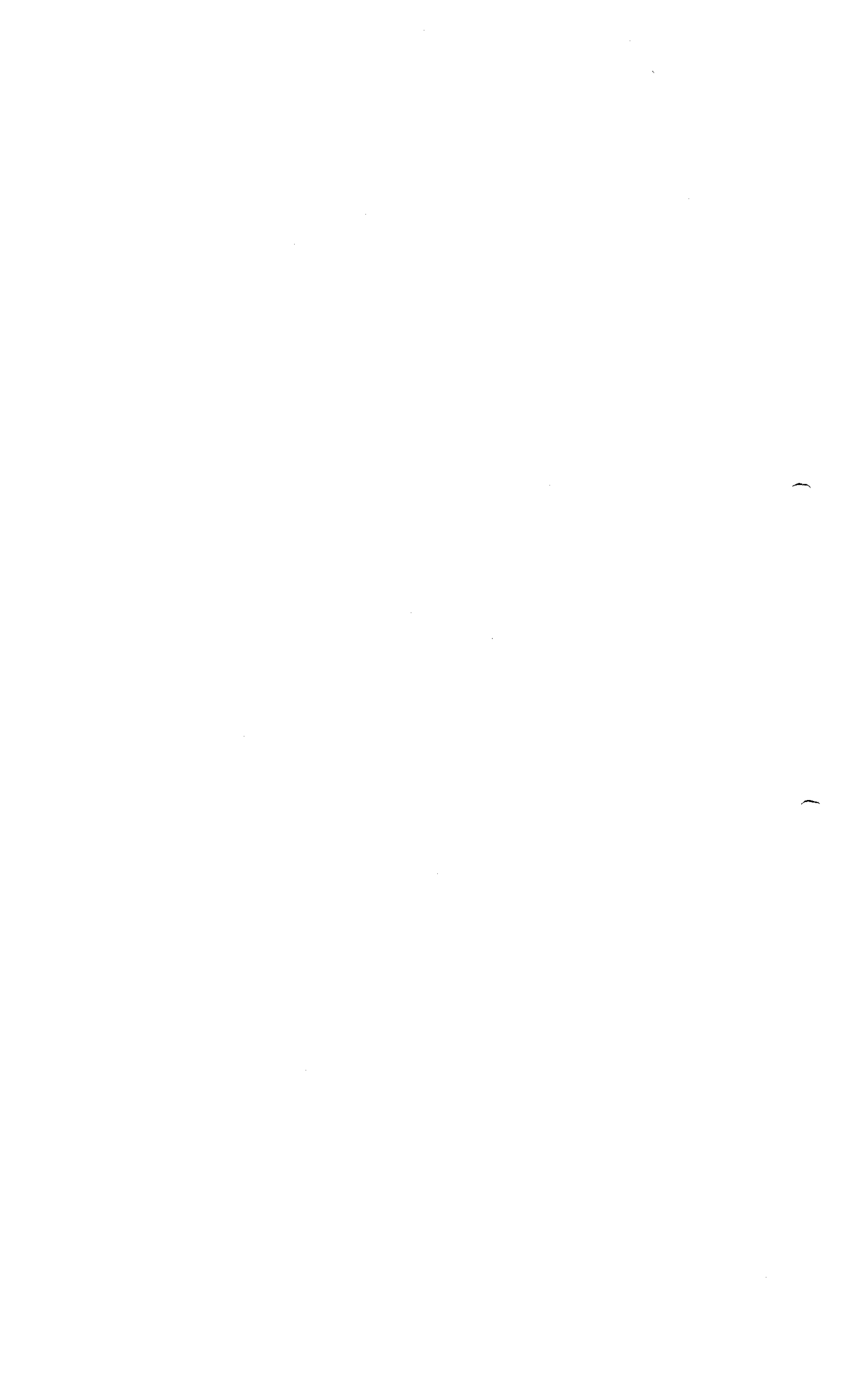
Method	:	viral titration of polio cytopathogenic effect on sensitive cells
Cell strain used	:	Hep 2
Temperature of incubation	:	36 ± 1° C
Test on	:	21.03.08
Test off	:	28.03.08

TIME	D0	D0 + 24H	D0 + 48H	D0 + 72H	D0 + 96H
Titer (CCID ₅₀ /ml)	10 ^{9.60}	10 ^{5.60}	≤10 ^{2.30}	≤10 ^{1.30}	≤10 ^{1.30}

Slope calculation : - 0.1521, Conforms



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MONOVALENT BULK - Type : 2
Lot Number : FA278342

Single harvest used : FA272631 –FA274124
Date of inactivation : 18.06.07
Inactivation method : 0.88% (w/v) Formaldehyde, 37°C, 12 days

Date of manufacture : 18.06.07
Volume : 95 300 ml
Storage temperature : +5°C ± 3°C
Monovalent bulk period of validity : 3 years
Expiry date : 18 JUNE 2010

CONTROLS:

Residual formaldehyde content

Method : Spectrophotometry
Date : 18.07.07
Result : 87.79 µg/ml - **Conforms**

Protein content

Method : Spectrophotometry
Date : 11.07.07
Result : 35.64 µg/ml

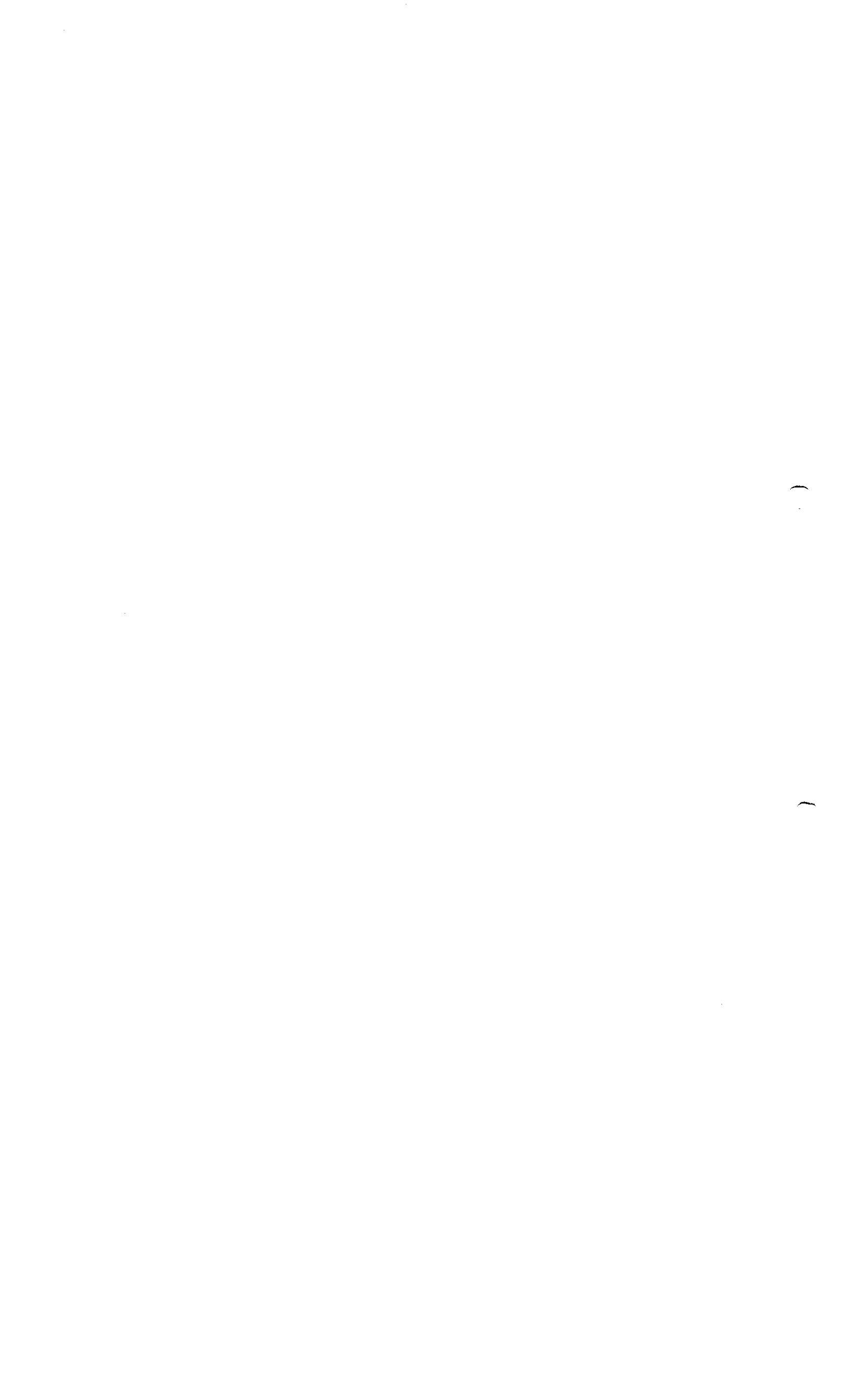
D Antigen content

Method : ELISA
Reference standard : 28.1.99
Date : 02.07.07
Result : 970 D.Antigen U/ml

Purity

Result : 36.746 ng of protein / D Antigen U - **Conforms**

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Bacterial and fungal sterility


Method used	:	Membrane filtration
Media	:	Thioglycollate medium Soybean Casein Digest medium
Temperatures	:	30-35° C 20-25° C
Volume tested	:	20 ml
Inoculum per Steritest	:	10 ml 10 ml
Volume of medium per Steritest	:	100 ml 100 ml
Test on	:	25.06.07
Test off	:	09.07.07
Result	:	No microbial growth


Inactivation kinetics

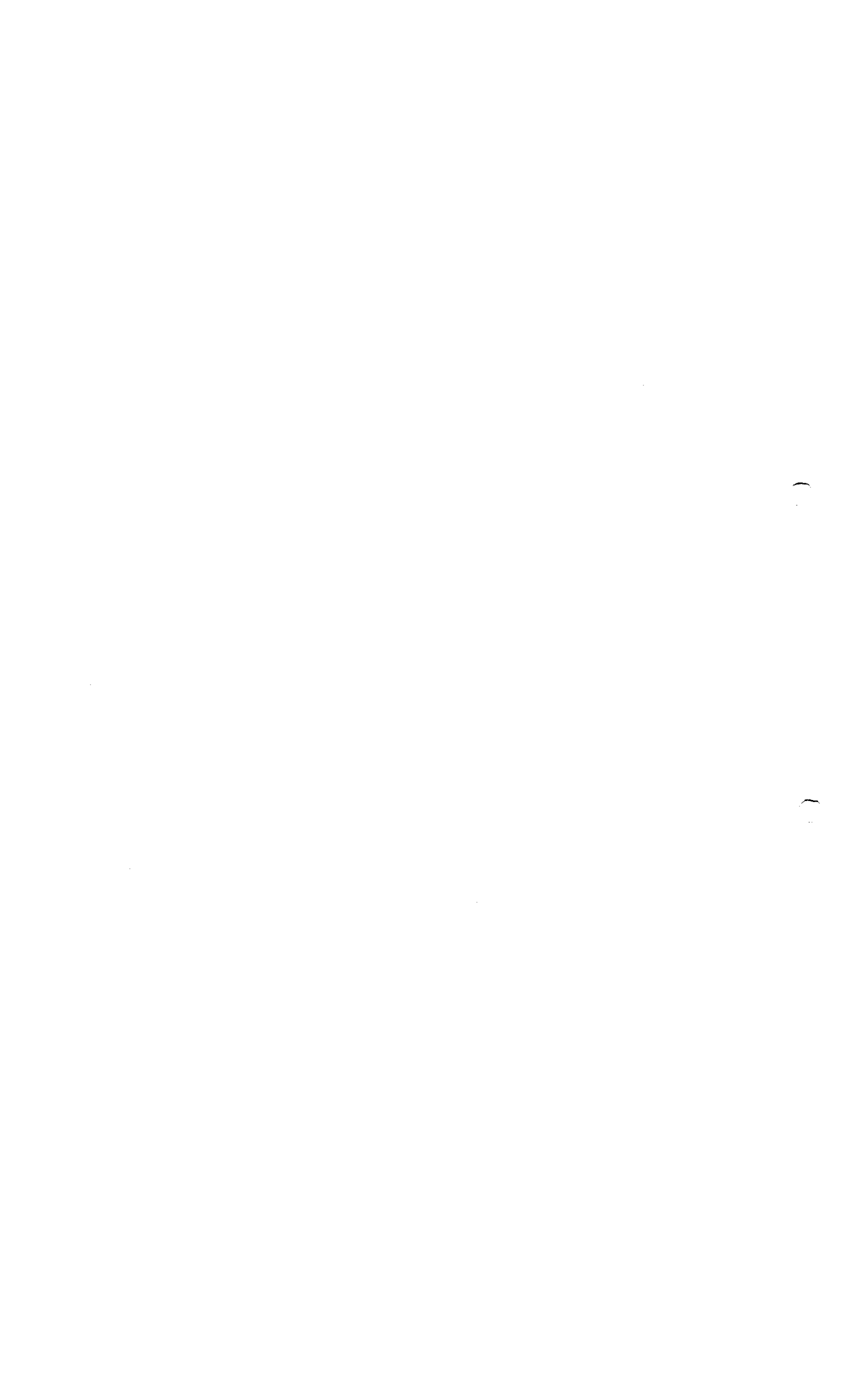
Method	:	viral titration of polio cytopathogenic effect on sensitive cells
Cell strain used	:	Hep 2
Temperature of incubation	:	36 ± 1°C
Test on	:	06.07.07
Test off	:	13.07.07

TIME	D0	D0 + 24H	D0 + 48H	D0 + 72H	D0 + 96H
Titer (CCID ₅₀ /ml)	10 ^{10.00}	10 ^{6.60}	≤10 ^{2.30}	≤10 ^{1.30}	≤10 ^{1.30}

Slope calculation : - 0.1604, Conforms


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MONOVALENT BULK - Type : 2
Lot Number : FA293397

Single harvest used : FA286930 – FA287531
Date of inactivation : 17.12.07
Inactivation method : 0.88% (w/v) Formaldehyde, 37°C, 12 days

Date of manufacture : 17.12.07
Volume : 96 800 ml
Storage temperature : +5°C ± 3°C
Monovalent bulk period of validity : 3 years
Expiry date : 17 DECEMBER 2010

CONTROLS:

Residual formaldehyde content

Method : Spectrophotometry
Date : 10.01.08
Result : 86.59 µg/ml - **Conforms**

Protein content

Method : Spectrophotometry
Date : 08.01.08
Result : 30.54 µg/ml

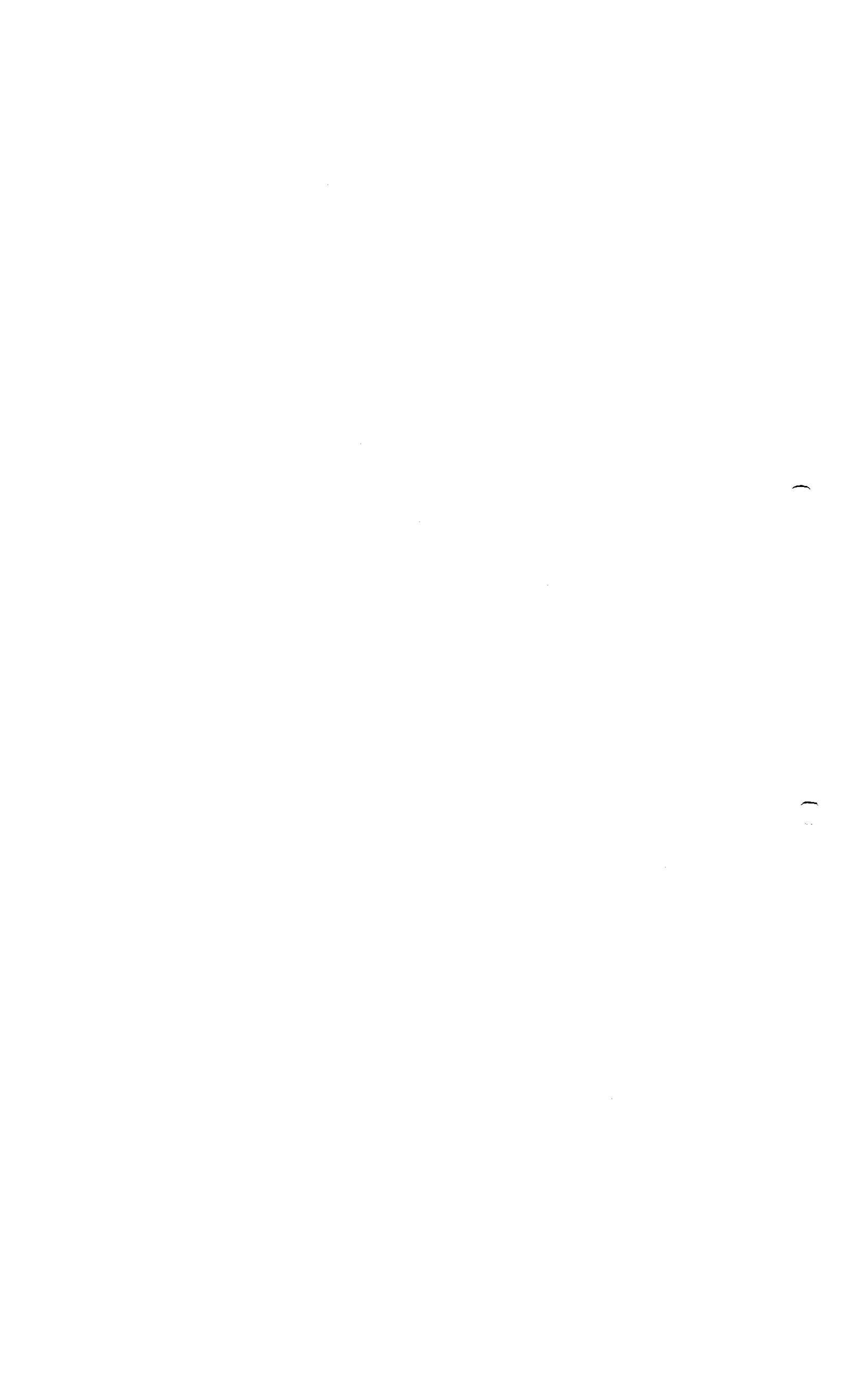
D Antigen content

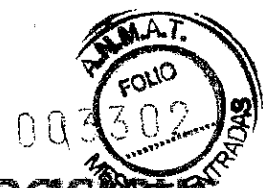
Method : ELISA
Reference standard : 28.1.99
Date : 14.01.08
Result : 843 D Antigen U/ml

Purity

Result : 36.2301 ng of protein / D Antigen U - **Conforms**

[Signature]
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Bacterial and fungal sterility

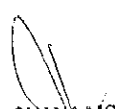
Method used	:	Membrane filtration	
Media	:	Thioglycollate medium	Soybean Casein Digest medium
Temperatures	:	30-35° C	20-25° C
Volume tested	:	20 ml	
Inoculum per Steritest	:	10 ml	10 ml
Volume of medium per Steritest	:	100 ml	100 ml
Test on	:	20.12.07	
Test off	:	03.01.08	
Result	:	No microbial growth	


Inactivation kinetics

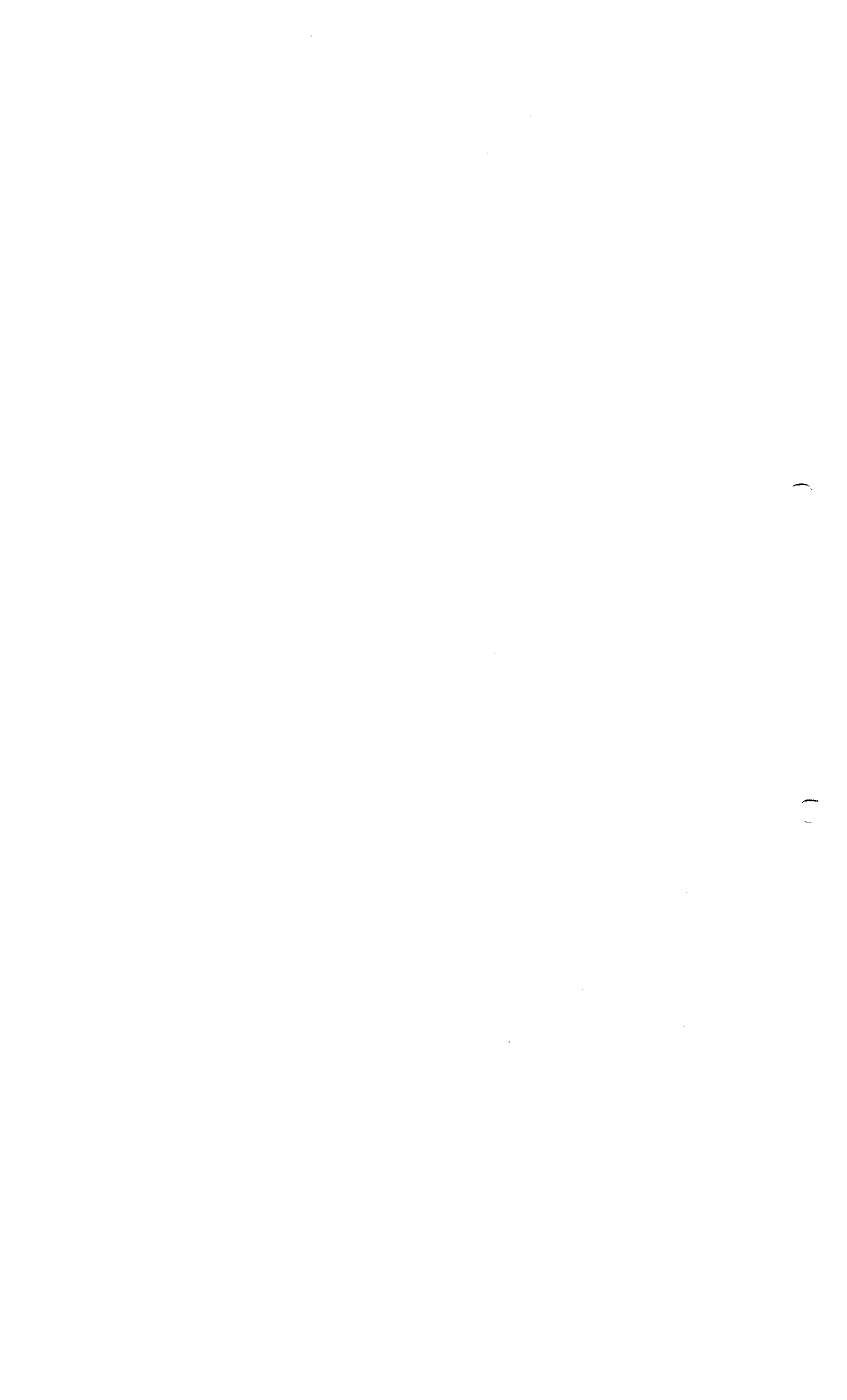
Method	:	viral titration of polio cytopathogenic effect on sensitive cells
Cell strain used	:	Hep 2
Temperature of incubation	:	36 ± 1° C
Test on	:	11.01.08
Test off	:	18.01.08

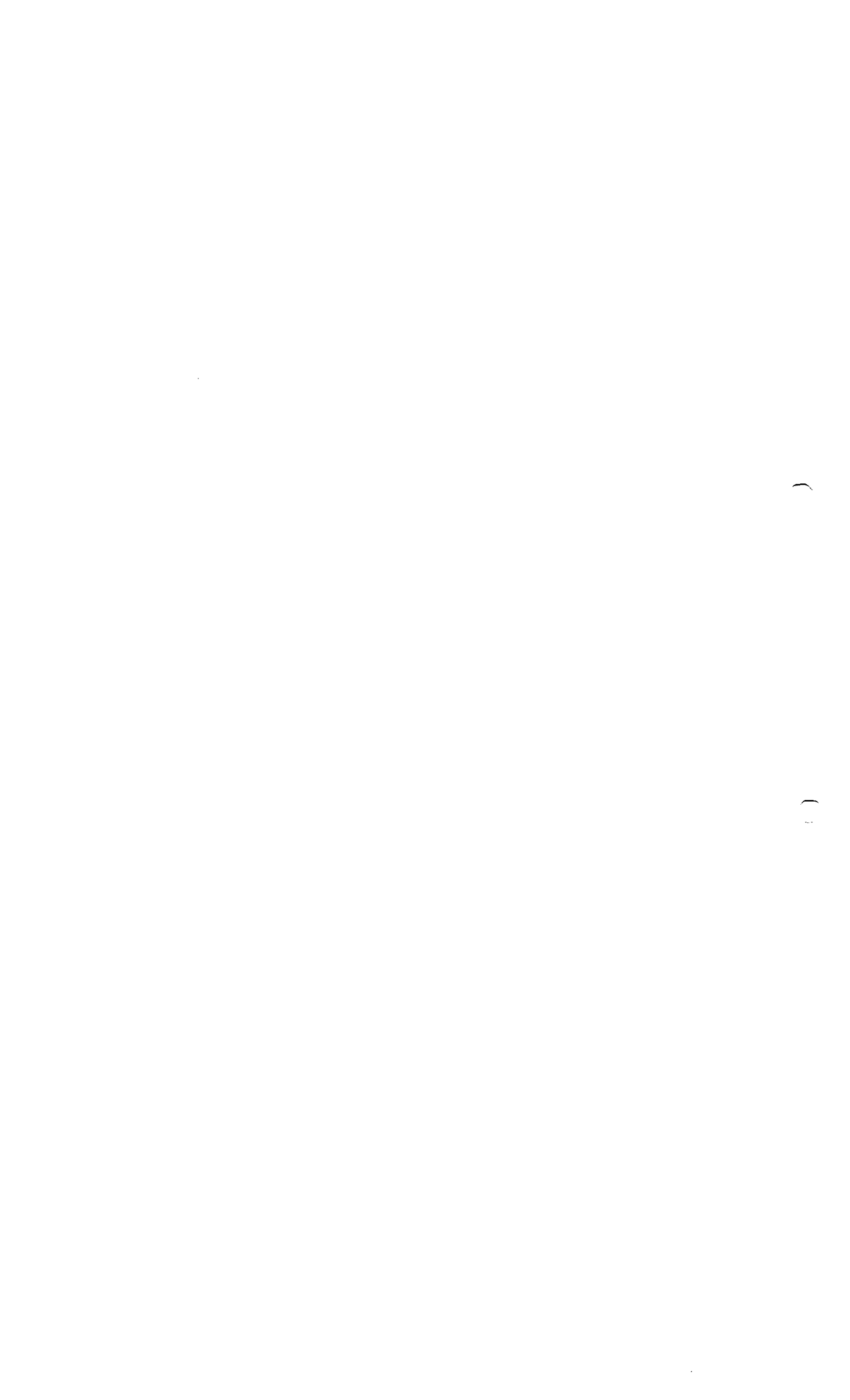
TIME	D0	D0 + 24H	D0 + 48H	D0 + 72H	D0 + 96H
Titer (CCID ₅₀ /ml)	10 ^{9.60}	10 ^{6.50}	10 ^{3.30}	≤10 ^{1.30}	≤10 ^{1.30}

Slope calculation : - 0.1313, Conforms


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MONOVALENT BULK - Type : 3
Lot Number : FA302425

Single harvest used	: FA292452
Date of inactivation	: 10.03.08
Inactivation method	: 0.88% (w/v) Formaldehyde, 37°C, 12 days
Date of manufacture	: 10.03.08
Volume	: 105 850 ml
Storage temperature	: +5°C ± 3°C
Monovalent bulk period of validity	: 3 years
Expiry date	: 10 MARCH 2011

CONTROLS:

Residual formaldehyde content

Method	: Spectrophotometry
Date	: 14.03.08
Result	: 84.78 µg/ml - Conforms

Protein content

Method	: Spectrophotometry
Date	: 13.03.08
Result	: 18.20 µg/ml

D Antigen content

Method	: ELISA
Reference standard	: 28.1.99
Date	: 25.03.08
Result	: 1 024 D Antigen U/ml

Purity

Result : 17.773 ng of protein / D Antigen U - **Conforms**

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