



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° S4313 (clinical batch) 144/180

D Antigen content

Method : ELISA
 Reference standard : 11/07/07
 Date : 13.11.08

	D Antigen unit/ml		
	Type 1	Type 2	Type 3
Product tested	467	88	339

Result : **Conforms**



Test for effective inactivation

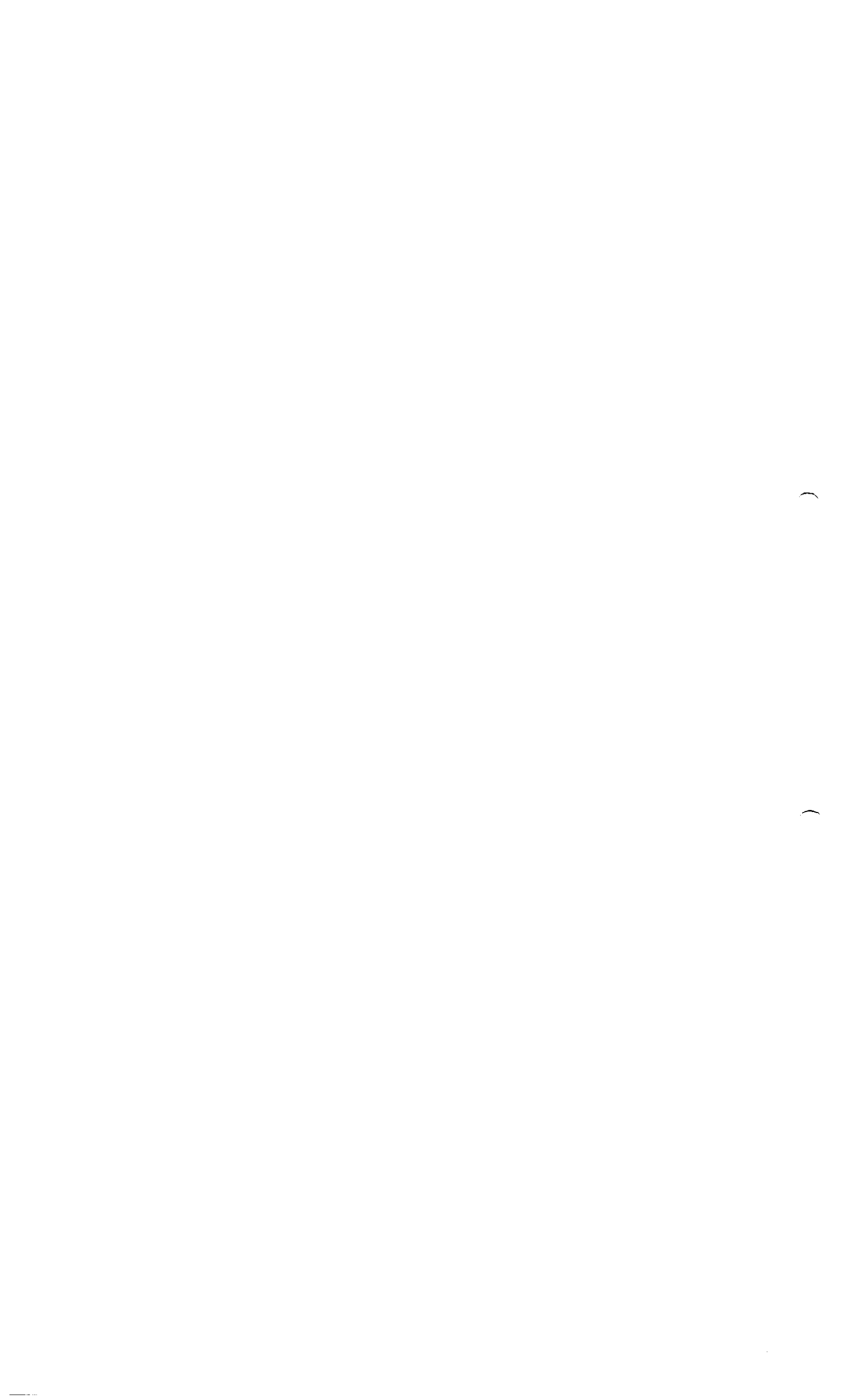
First test

Method : Cytopathogenic effect on sensitive cells
 Cell strain : Vervet
 Volume tested : 3000 theoretical human doses
 Virulence challenge : viral suspension (type 1, 2, 3)
 about 100-300 CCID₅₀/ml
 Temperature of incubation : 37 ± 1°C
 Test on : 16.12.08
 Test off : 06.01.09

	Inoculation date	Reading date			Result
		At 7 th day	At 14 th day	At 21 st day	
primary test Vervet – V1086	16.12.08	23.12.08	30.12.08	06.01.09	no CPE
subculture at 7 th day Vervet – V1088	15.01.09		30.01.09		no CPE
subculture at 14 th day Vervet – V1088	15.01.09		30.01.09		no CPE
subculture at 21 st day Vervet – V1088	15.01.09		30.01.09		no CPE
virulence challenge Vervet – V1086	07.01.09	14.01.09			CPE

Result : **No cytopathic effect (CPE)**


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- F - HAEMOPHILUS type b CONJUGATE


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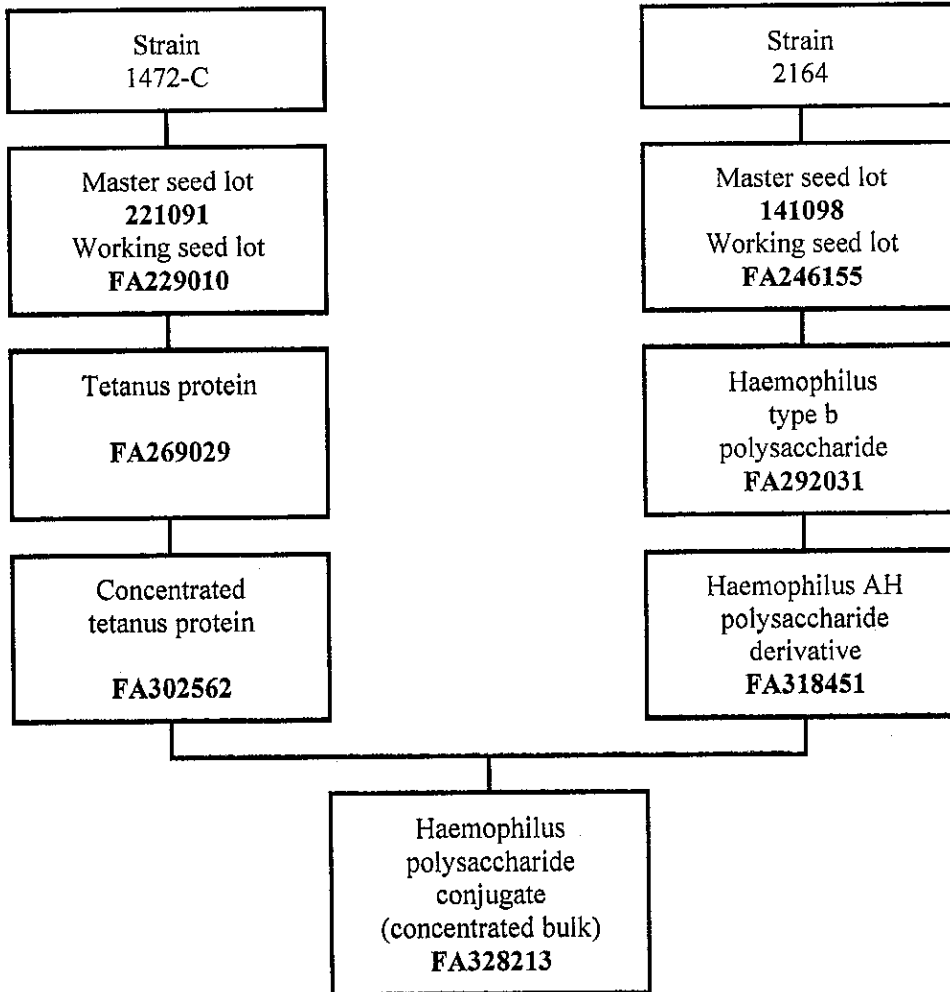
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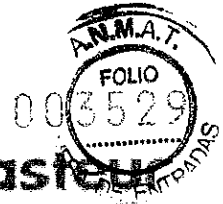
PRODUCTION FLOW SHEET




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HAEMOPHILUS INFLUENZAE
Strain : Haemophilus Influenzae 2164

STRAIN

Name : Haemophilus influenzae type b – strain 1482
Origin : Dr John ROBBINS (FDA)
Bethesda – Maryland 20014
Received : 12.12.75
Institut Mérieux number : IM 2164

HAEMOPHILUS INFLUENZAE
Master seed lot n° 141098

Strain number : IM 2164
Preparation date : 14.10.98
Release date : 11.09.01

CONTROLS

- Purity
Identification
- Morphology
 - Growth characteristics
 - Biochemical characteristics
 - Antigenic characteristics

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HAEMOPHILUS INFLUENZAE
Working seed lot n° FA246155


Master seed Lot n° : 141098
Preparation date : 23.06.06
Release date : 18.04.07

CONTROLS

- Purity
- Identification
 - Morphology
 - Growth characteristics
 - Biochemical characteristics
 - Antigenic characteristics

The tests results show that working seed lot has the same characteristics as the master seed lot.


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influenzae type b conjugate vaccine (adsorbed) lot n° S4313 (clinical batch) 150/180

TETANUS TOXOID
Strain : Clostridium tetani 1472-C

STRAIN


Name : Harvard 49205 strain identified by the n°Y-IV-5A
Origin : Rijks Instituut (RIV), Bilthoven
Netherlands
Received : 17.11.82
Institut Mérieux number : IM 1472-C


TETANUS TOXOID
Master seed lot n° 221091

Strain : IM 1472-C
Preparation date : 22.10.91
Release date : 14.11.91

CONTROLS

- Purity
Identification
- Morphology
 - Growth characteristics
 - Biochemical characteristics


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TETANUS TOXOID
Working seed lot n°FA229010


Master seed lot n° : 221091
Preparation date : 20.12.05
Release date : 19.01.09

CONTROLS

- Purity
- Identification
 - Morphology
 - Growth characteristics
 - Biochemical characteristics

The tests results show that working seed lot has the same characteristics as the Master seed lot.


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