3.2.A.4 Certificate of Analysis (CoA)

3.2.A.4.1 CoA for Serum used in the CHOK1 adaptation

HyClone®

HyClone New Zealand
Omokoroa Farm
441 Old Highway
P.O. Box 658
Tauranga, New Zealand

CERTIFICATE OF ANALYSIS

Product: FOETAL BOVINE SERUM
New Zealand Sourced
Triple 0.1µm Filtered

Catalogue Number: SH30406.02

Lot Number: DPH0176 **Manufacturing Date:** AUG/2004

Total Batch Volume: 1488.2 L **Expiration Date:** *AUG/2012

Test/Method	Specification	Units	Result
Endotoxin (Limulus Amebocyte Lysate – Gel Clot)	≤ 20	EU/mL	<0.5
Haemoglobin (Spectrophotometric)	≤ 25	mg/dL	2
Sterility Testing (USP24 or current) Bacteria & Fungi	No Growth		No Growth
Virus Testing (9 CFR 113.53)			
Fluorescent Antibody			
Bluetongue	Not Detected		Not Detected
Bovine Adenovirus	Not Detected		Not Detected
Bovine Parvovirus	Not Detected		Not Detected
Bovine Respiratory Syncytial Virus	Not Detected		Not Detected
Bovine Virus Diarrhoea	Not Detected		Not Detected
Rabies	Not Detected		Not Detected
Reovirus	Not Detected		Not Detected
Cytopathogenic Agents - e.g. IBR	Not Detected		Not Detected
Haemadsorbing Agents - e.g. PI3	Not Detected		Not Detected
Mycoplasma			
(Large Volume, Direct Culture)	Not Detected		Not Detected
(Hoechst DNA Stain)	Not Detected		Not Detected

The raw material used to produce this batch of serum has been sourced exclusively from clinically healthy cattle which were born and maintained in a country which is officially recognised as being free from Bovine Spongiform Encephalopathy (BSE) namely New Zealand.

HyClone Foetal Bovine Serum products have been granted a Certificate of Suitability to the European Pharmacopoeia Monograph. (Certificate # RO-CEP 2000-211)

23 Jan 09

Harshila Mistry
QA/QC Manager
*Amended 20 Jan 09 (Expiry Date)

bioprocess containers • media • buffers • reagents • serum-free media • FBS alternatives • sera

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HyClone®

Product: **Fetal Bovine Serum**

Collected in South America, Processed in China

Catalog #: **SV30087**
Lot #: **NUK0201**
Filtration: **Triple 0.1 µm Filtered**

Manufacturing Date: **Oct/2009**
Expiration Date: **Oct/2014**
Total Lot Volume (Liters): **1466.7**

Certificate of Analysis

Test	Specification	Units	Results
Endotoxin (Limulus Amebocyte Lysate-Gel Clot)	≤ 25	EU/ml	< 5
Hemoglobin (Spectrophotometric)	≤ 25	mg/dl	9.06
Sterility Testing (Bacteria and Fungi)	No Growth		No Growth
Virus Screening (Bovine Viral Diarrhea Virus)	Not Detected		Not Detected
Mycoplasma			
(Large Volume, Direct Culture)	Not Detected		Not Detected
(Hoechst DNA Stain)	Not Detected		Not Detected
Growth Promotion			
BHK21	FIO		Satisfactory

This product was manufactured from Fetal Bovine Blood collected in South America. This product has not come from cattle born, raised, shipped through or slaughtered in countries where BSE is known to exist.

Quality Control Department

12 Nov 2009.
Date

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[KN035, Alphamab Co., Ltd]