

Certificate of Analysis CloneDetect Human IgG (H+L) Specific, Fluorescein K8200

Batch #

CDA0821A

Full Description	Sheep anti-human IgG (H+L), polyclonal, Fluorescein- conjugated. Sterile, azide free
Origin of Host Species	USA Sheep kept at a registered technical plant (1774/2002 registration # VT-TEC-0002) under regular veterinary
	supervision Inspected to confirm the absence of following:
	Foot and Mouth Disease; Rift Valley Fever; Rinderpest; Vescular Stomatitis; Peste Des Petits Rumaninants; Blue Tongue; Epizootic Hemorrhagic Disease; Scrapie
	The sheep had no contact with animals of a lesser health.
Immunogen	Human IgG (H+L) purified from human serum
Preparation	Antiserum is prepared by immunising sheep with the above immunogen. Cross reactivity with bovine serum proteins has been minimised by insoluble adsorption. The antiserum is then conjugated with fluorescein. Unreacted fluorochrome is removed by gel filtration.
Format	Affinity purified sheep immunoglobulin conjugated to fluorescein-5-EX, Succinimidyl Ester
Specificity	The unconjugated immunoglobulin was shown to be specific by immunoelectrophoresis and double diffusion
Method of Purification	Affinity chromatography

Viral Testing	Negative. Product was found to be free of viral contaminants based on: qualified real-time PCR screening for rodent virus panels. Tests performed by Charles River (full report available on request).
Mycoplasma Testing	Negative. Product is assayed following a broth enrichment step using a Testing for Presence of Mycoplasma Using Broth Culture Growth Enrichment and RT-PCR Detection assay GP.V900.01. Assay meets or exceeds the requirements of 21 CFR 610.30, 1993 PTC, and EP. Test performed by Charles River (report available on request).
Appearance	Clear yellow solution
Concentration	10,000 U/ml
Volume	1.0 ml
Total Amount	0.75 mg
Dye : Protein Ratio	3.3
Buffer	Phosphate Buffered Saline pH7.2
Preservatives/Stabilisers	1% BSA (Manufacture: Proliant ; Catalog No: 68100 ; Lot BB02550101)
Sterility	0.2μm sterile filtered Product tested, no bacterial or fungal growth found after 72 hours incubation
Expiry Date	12 months from receipt of product

This product has been manufactured to ISO9001:2015 Quality Assurance guidelines

For research use only Store at 2 – 8°C

Signed: Kiew-Khiem Nguyen

Production Biologist

Date: 28-OCT-2021