

Certificate of Analysis

CloneDetect

Human IgG (H+L) Specific, Fluorescein BSA Free K8202

Batch #	CDT1112A
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Full Description	Sheep anti-human IgG (H+L), polyclonal, Fluorescein-conjugated. Sterile, BSA and 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; Vesicular Stomatitis; Peste Des Petits Ruminants; 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	Fluorescein-conjugated IgG, liquid
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: A 14 day <i>in vitro</i> assay monitoring CPE (cytopathic effects), HA (haemagglutination) and HAD (haemadsorption) using 3 detector cell lines (MRC5 cells / ATCC CCL171, L929 cells / ATCC CCL1, CHO-K1 / ATCC CCL61). Tests performed by Charles River (full report available on request).

Mycoplasma Testing	Negative. Product is assayed on broth and agar on indicator cells using the enhanced procedure and includes a mycoplasma mastitis assay. 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	3.2
Buffer	Phosphate Buffered Saline pH7.2
Sterility	0.2µm sterile filtered Product tested, no bacterial or fungal growth found after 72 hours incubation
Date of manufacture	08 November 2013
Expiry Date	12 months from receipt of product

This product has been manufactured to ISO9001:2008 Quality Assurance guidelines

For research use only Store at 2°C – 8°C

Signed:

Date: 02 January 2013



Production Supervisor