

Certificate of Analysis

CloneDetect

Human IgG (H+L) Specific, Fluorescein 5ml Atomiser

K8201

Batch #	CDA1215A
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Full Description	Sheep anti-human IgG (H+L), polyclonal, Fluorescein-conjugated. Sterile, azide free. In atomiser spray applicator
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
Functionality Test	This product contains K8200 diluted in PBS, the K8200 component is tested and validated in a functional assay on <i>ClonePix™ FL</i>
Viral Testing	Negative. The K8200 component 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 BioReliance (full report available on request).
Mycoplasma Testing	Negative. The K8200 component is assayed on broth and agar on indicator cells using the enhanced procedure and includes a mycoplasma assay. Assay meets or exceeds the requirements of 21 CFR 610.30, 1993 PTC, and EP. Test performed by BioReliance (report available on request).
Appearance	Clear yellow solution
Concentration	2,000 U/ml

Volume	5.0 ml
Total Amount	0.75 mg
Dye : Protein Ratio	2.9
Buffer	Phosphate Buffered Saline pH7.2
Preservatives/Stabilisers	0.2% BSA (Sigma Product: A3059 Lot SLBD5581V)
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 & ISO13485 Quality Assurance guidelines

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

Signed: *Kieu-Khiem Nguyen*

Date: 21 DEC 2015

Production Supervisor