

Certificate of Analysis

CloneDetect

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

K8201

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| Batch # | CDA0316A |
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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 |

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| 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: 11 MAR 2016

Production Biologist