

Certificate of Analysis CloneDetect Human IgG (H+L) Specific, Fluorescein K8400

Full Description	Goat anti-human IgG (H+L), polyclonal, FITC Fluorescein-conjugated. Sterile, azide free
Origin of Host Species	USA Goat kept at a USDA registered technical plant (registration # 23-R- 0114) under regular veterinary supervision and inspection. Raw materials are collected from animals veterinary-certified clinically free of signs of bovine spongiform encephalopathy (BSE), transmissible spongiform encephalopathy (TSE), foot and mouth disease (FMD). The goat had no contact with animals of a lesser health and have remained healthy during raw materials collection.
Immunogen	Human IgG (H+L) purified from human serum
Preparation	Antiserum is prepared by immunizing goat with the above immunogen. Cross reactivity with bovine, horse, mouse serum proteins has been minimized by insoluble adsorption. The purified immunoglobulin is then conjugated with fluorescein. Unreacted fluorochrome is removed by gel filtration.
Format	Affinity purified goat immunoglobulin conjugated to fluorescein-5- isothiocyanate
Specificity	This product reacts with whole molecule human IgG. It may also react with the light chains of other human immunoglobins. No antibody was detected against non-immunoglobin serum proteins by immuno- electrophoresis and/or ELISA.
Method of Purification	Immunoaffinity chromatography using antigens coupled to agarose beads
Purified Antibody/Starting Materials Identification ID	159353
Viral Testing	Negative. Product was found to be free of viral contaminants based on: qualified real-time PCR screening for comprehensive rodent virus panels. Tests performedby Charles River (report available on request).

Document Revised on September 2, 2022 to correct "Expiry Date" from "9 months from shipment of product" to "6 months from shipment of product"



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	> 3.5
Buffer	Phosphate Buffered Saline pH 7.6
Preservatives/Stabilizers	1.5% Bovine Serum Albumin (IgG-Free, Protease-Free)
Sterility	0.2μm sterile filtered.
Expiry Date	6 months from shipment of product
Storage	2 – 8°C

This product has been manufactured to ISO 9001:2015 Quality Assurance guidelines

For research use only

Signed: Kiew-Khiem Nguyen

Date: 23-AUG-2022

Production Biologist