

DESCRIPTION	
Species Reactivity	Human
Specificity	Detects human CD3 in a flow cytometry-based assay using Jurkat cells
Source	Mouse monoclonal antibody, OKT3 clone, reformatted to human IgG1 isotype Produced recombinantly from a stable HEK293 cell line Manufactured and tested under cGMP guidelines
Purification	Protein G purified from cell culture supernatant
Immunogen	Human T lymphocytes
Formulation	Lyophilized from a 0.2 µm filtered solution in PBS with Trehalose. See Certificate of Analysis for details.

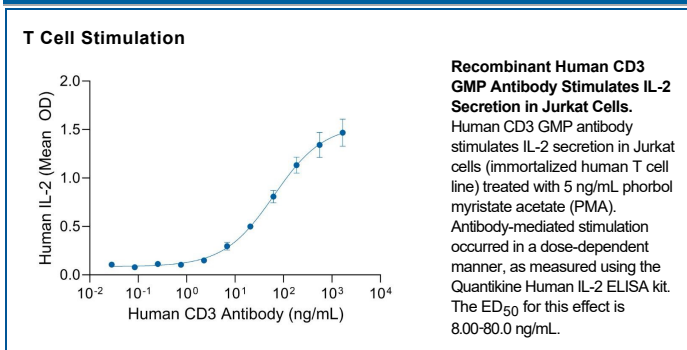
SPECIFICATIONS	
Purity	≥95%, by SDS-PAGE with quantitative densitometry by Coomassie® Blue Staining.
Endotoxin Level	<0.10 EU per 1 µg of the antibody by the LAL method.
Host Cell Protein	≤0.500 ng per µg of antibody when tested by ELISA
Host Cell DNA	≤0.0100 ng per µg of antibody when tested by PCR
Mycoplasma	Negative when tested in a ribosomal RNA hybridization assay
Activity	Measured by its ability to induce IL-2 secretion by Jurkat human acute T cell leukemia cells. Freeman, G.J. <i>et al.</i> (1993) Science 262 :909. The ED ₅₀ for this effect is 8.00-80.0 ng/mL
Aggregation	≤10% aggregation when tested by SEC

APPLICATIONS

Please Note: Optimal dilutions should be determined by each laboratory for each application. General Protocols are available in the Technical Information section on our website.

	Recommended Concentration	Sample
T Cell Stimulation	1 µg/mL	Human PBMCs

DATA



PREPARATION AND STORAGE

Reconstitution	Reconstitute at 0.5 mg/mL in sterile PBS.
Shipping	The product is shipped with polar packs. Upon receipt, store it immediately at the temperature recommended below.
Stability & Storage	Use a manual defrost freezer and avoid repeated freeze-thaw cycles. <ul style="list-style-type: none"> • A minimum of 12 months when stored at ≤ -20 °C as supplied. Refer to lot specific COA for the Use by Date. • 1 month, 2 to 8 °C under sterile conditions after reconstitution. • 6 months, ≤ -20 °C under sterile conditions after reconstitution.

BACKGROUND

The Bio-Techne CD3 GMP antibody is derived from the OKT3 clone and binds specifically to the epsilon subunit of the CD3 complex. CD3 (cluster of differentiation 3) is a protein complex and T cell co-receptor that is critical for the activation of T cells. Specifically, the CD3 complex is crucial in transducing antigen-recognition signals into the cytoplasm of T cells and in regulating the cell surface expression of the TCR complex. T cell activation through the antigen receptor (TCR) involves the cytoplasmic tails of the CD3 subunits CD3 gamma, CD3 delta, CD3 epsilon and CD3 zeta. These CD3 subunits are structurally related members of the immunoglobulin super family encoded by closely linked genes on human chromosome 11. The CD3 components have long cytoplasmic tails that associate with cytoplasmic signal transduction molecules. This association is mediated at least in part by a double tyrosine-based motif present in a single copy in the CD3 subunits. The CD3 antigen is present on 68-82% of normal peripheral blood lymphocytes, 65-85% of thymocytes and Purkinje cells in the cerebellum.

MANUFACTURING SPECIFICATIONS

GMP Antibodies

R&D Systems, a Bio-Techne Brand's GMP Antibodies are produced according to relevant sections of the following documents: USP Chapter 1043, Ancillary Materials for Cell, Gene and Tissue-Engineered Products, and Eu. Ph. 5.2.12, Raw Materials of Biological Origin for the Production of Cell-based and Gene Therapy Medicinal Products.

R&D Systems' quality focus includes:

- Manufactured and tested under an ISO 9001:2015 and ISO 13485:2016 certified quality system
- Documented processes and QA control of documentation and process changes
- Personnel training programs
- Raw material inspection and supplier qualification/monitoring
- Fully validated equipment, processes and test methods
- Equipment calibration monitored and scheduled using a computerized calibration program
- Facility maintenance, safety programs and pest control
- Variances dispositioned using material review process
- Robust product stability program

R&D Systems strives to provide our customers with the analytical characteristics of each product so that customers may determine whether our products are appropriate for their research. The Certificate of Analysis provided contains the following lot specific information:

- Purity (SDS-PAGE)
- Aggregation (SEC)
- Endotoxin (LAL method, tested per USP<85> and Ph. Eur. 2.6.14 guidelines)
- Residual Host Cell Protein and Host Cell DNA
- Mycoplasma testing
- Post-bottling lot-specific bioassay results (compliance with an established range) and results of microbial testing according to USP <71>

Additional testing and documentation requested by the customer can be arranged at an additional cost.

Production records and facilities are available for examination by appropriate personnel on-site at R&D Systems in Minneapolis, Minnesota USA.

R&D Systems sells GMP grade products for preclinical or clinical *ex vivo* use. They are not for *in vivo* use. Please read the following End User Terms prior to using this product.

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