

Certificate of Analysis

Product:	16D9 anti Alpha-gal hIgE mAb
Product Code:	E-16D9
Lot Number:	xxxxx
Antibody Clone:	16D9-IgE
Origin:	Monoclonal antibody derived from a patient allergic to red meat.
Specificity:	Alpha-gal (galactose- α -1,3-galactose)
Total IgE Concentration:	50,000 IU/mL (+/- 20%) based on ImmunoCAP using WHO International Standard for Immunoglobulin E (IgE) (NIBSC code 11/234).
Quantity:	10,000 IU in 0.2mL (1.0 IU = ~2.4ng IgE)
Formulation:	In phosphate buffered saline, pH 7.4 and 0.05% Tween-20. 0.22 μ m filtered, preservative free.
Specific IgE Concentration:	Lot specific concentration (IU/mL) based on ImmunoCAP using natural Gal-alpha-1,3-Gal (alpha-Gal) (product code: o215)
Storage/Handling:	Maintain at -20°C for up to 12 months. Avoid repeated freeze-thaw cycles. Store product undiluted. No stability data available.

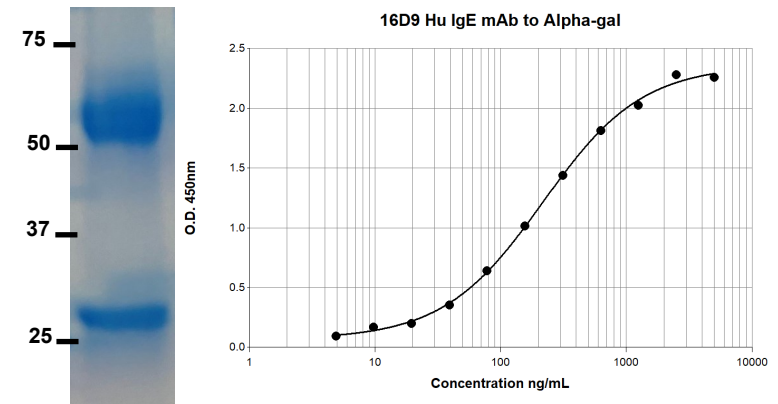
Applications include:

- QC and validation of purified allergens for molecular diagnostics
- *In vitro* IgE diagnostic tests, calibrators, controls, alternatives to human sera
- Molecular reference standards for IgE
- Epitope analysis and localization of IgE epitopes
- Mast cell/basophil activation assays and histamine release
- Animal models of anaphylaxis

For research or *in vitro* diagnostic use only:
Not for human *in vivo* or therapeutic use

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16D9 Human IgE mAb to Alpha-gal Purity and Titration Curve



Reference

Khatri K. et. al., Human IgE monoclonal antibody recognition of mite allergen Der p 2 defines structural basis of an epitope for IgE cross-linking and anaphylaxis *in vivo*, *PNAS Nexus*, 2022; 0:1-0.

Wurth, M.A. et al., Human IgE mAbs define variability in commercial *Aspergillus* extract allergen composition, *JCI Insight*. 2018;3 (20):e123387.

Bazaraal, M. and Hamburger, R.N., Standardization and stability of immunoglobulin E, *J Allergy Clin Immunol* 1972; 49:189-191. PMID 4622102.

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