



DIAGNOSTIC AUTOMATION, INC.

23961 Craftsman Road, Suite D/E/F, Calabasas, CA 91302

Tel: (818) 591-3030 Fax: (818) 591-8383

onestep@rapidtest.com

technicalsupport@rapidtest.com

www.rapidtest.com



See external label



2°C-8°C



Σ=96 tests



Cat # 1801Z

Total Human IgE Assay

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Test	Total Human IgE Assay
Method	Enzyme Linked Immunosorbent
Principle	Peroxidase – Conjugated ELISA
Detection Range	0-400IU/mL
Sample	10µl serum
Specificity	N/A
Sensitivity	0.05 µg/mL
Total Time	4 hours 30 mins
Shelf Life	12-14 months

** Laboratory results can never be the only base of a medical report. The patient history and further tests have to be taken into account*

Intended Use

To quantitate total human Immunoglobulin E (IgE)

Principle of Procedure

Solid phase capture sandwich ELISA assay using a microwell format.

Shelf Life

The expiration date for the package and each component is stated on the label(s). Store components at 2°-8°C, except for standard, which should be stored at -20°C.

Patient and Standard Dilutions

Patients and standards are diluted in the wells by adding 10uL to 90uL of specimen diluent. The specimen diluent alone is used for a blank.

Materials Supplied

1. Anti-Human IgE coated microwell strips 12x8 with plastic frame
2. HRP conjugated goat anti-human IgE -12mL
3. IgE standard (Low, Medium, High)
4. TMB/peroxide substrate color developer –12mL
5. IgE specimen diluent (Specimen Diluent Green II) –1 x 60mL
6. Sulfuric acid termination reagent (0.5N) –12mL
7. 15 X Wash buffer concentrate – 60mL

Limitations of the Procedure

No single assay should be used as the only basis for arriving at a diagnostic conclusion. For research use only.

Dynamic Range

0IU/mL-400IU/mL

For the higher dynamic range dilute standards and specimen 1:5 with the provided diluent before running assay.

Reproducibility

C.V. 6%-10% depending upon the region of the standard curve

Assay Procedure

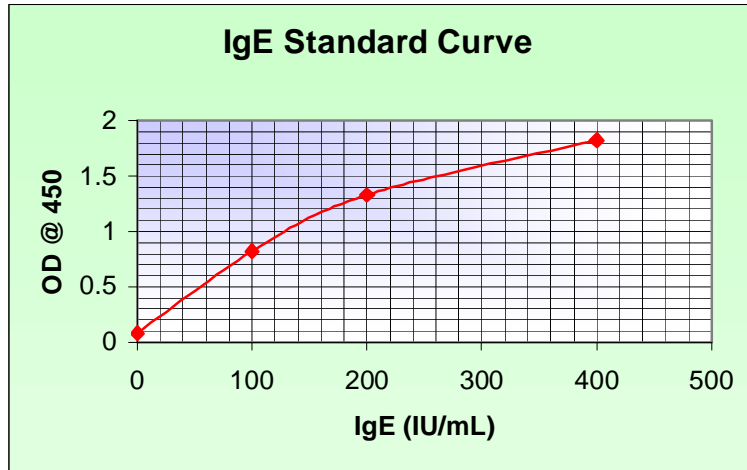
*Allow each reagent to reach room temperature before use

1. Add 10uL of specimen or standard to each microwell
2. Add 90 ul of specimen diluent to each standard or specimen well.
3. Incubate at room temperature for 2 hours.
4. Decant and wash each microwell four times with wash buffer (dilute buffer 1:15 with reagent grade water)
5. Add 100uL of HRP conjugated goat anti-human IgE to each well
6. Incubate at room temperature for 2 hours.
7. Decant and wash as in step 3
8. Add 100uL of TMB/peroxide substrate and incubate at room temperature for 30 minutes

9. Terminate the reaction with 100uL of 0.5N sulfuric acid
10. Zero the microwell reader at 450nm using the specimen diluent zero control well
11. Determine the optical density (O.D.) of the remaining wells
12. Construct a standard curve using the O.D. values obtained for each of the standards
13. Interpolate the unknowns from the standard curve

Note: Constructed 4 Parameter Curve displayed.

Typical Standard Curve



Date Adopted	Reference No.
2010-12-14	DA-Total Human IgE Assay-2010



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