



DIAGNOSTIC AUTOMATION, INC.

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IVD	See external label	2°C-8°C	Σ=96 tests	REF Cat # 1803-09
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Total Human IgG Assay

Cat # 1803-09

Test	Total Human IgG Assay
Method	Enzyme Linked Immunosorbent
Principle	Peroxidase – Conjugated ELISA
Detection Range	0.156 µg/mL - 1µg/mL
Sample	10µl serum
Specificity	N/A
Sensitivity	5 IU/mL
Total Time	~105min
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 G (IgG)

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

Dilute each serum or plasma specimen to be tested initially 1:100 with phosphate buffered saline (PBS) *e.g. 10ul specimen into 990 uL PBS*, then subdilute 1:100 as before. Finally, dilute 1:10 in the IgG specimen diluent provided. The final dilution factor will be 1:100,000. Prepare serial two fold dilutions of the human IgG standard: Neat, 1:2, 1:4, 1:8 etc. with the specimen diluent provided. Use the specimen diluent alone as the blank control well.

Materials Supplied

1. Anti-Human IgG coated microwell strips 12x8 with plastic frame
2. HRP conjugated goat anti-human IgG-12mL
3. IgG standard (pre-diluted 1:100,000) – 1 mL
4. TMB/peroxide substrate color developer –12mL
5. IgG specimen diluent -1 x 60MI
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

0.156µg/mL to 1µg/mL.

Reproducibility

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

Assay Procedure

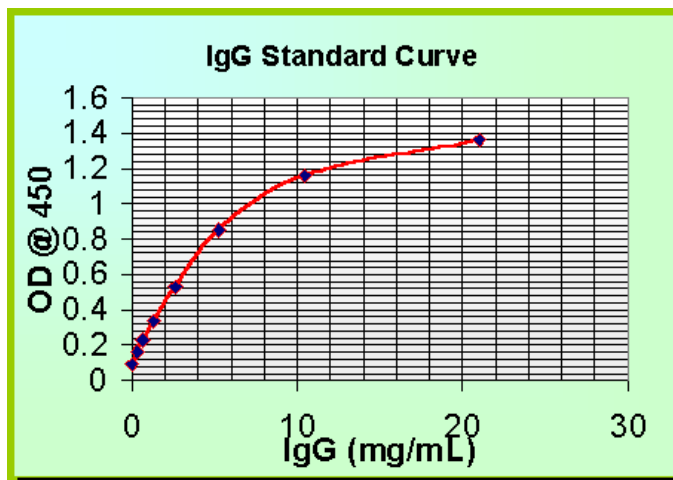
*Allow each reagent to reach room temperature before use

1. Add 100uL of *diluted* specimen or standard to each microwell
2. Incubate at room temperature for 45 minutes
3. Decant and wash each microwell four times with wash buffer (dilute buffer 1:15 with reagent grade water)
4. Add 100uL of HRP conjugated goat anti-human IgG to each well
5. Incubate at room temperature for 45 minutes

6. Decant and wash as in step 3
7. Add 100uL of TMB/peroxide substrate and incubate at room temperature for 15 minutes
8. Terminate the reaction with 100uL of 0.5N sulfuric acid
9. Zero the microwell reader at 450nm using the specimen diluent zero control well
10. Determine the optical density (O.D.) of the remaining wells
11. Construct a standard curve using the O.D. values obtained for each of the standards
12. Interpolate the unknowns from the standard curve

Note: Constructed 4 Parameter curve displayed.

Typical Standard Curve



Date Adopted	Reference No.
2005-09-27	DA-Total Human IgG Assay-2008

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