



DIAGNOSTIC AUTOMATION, INC.

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

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

onestep@rapidtest.com

technicalsupport@rapidtest.com

www.rapidtest.com

IVD



See external label



2°C-8°C



Σ=96 tests

REF

#1804-9

Total Human IgM Assay

Intended Use:

To quantify total human Immunoglobulin M (IgM)

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 all components at 2-8°C, except for the standard, which should be stored at -20°C.

Patient and Standard Dilutions:

Dilute each serum or plasma specimen to be tested 1:1,000 with Phosphate Buffered Saline (PBS). * PBS not provided. Subdilute 1: 10 with the IgM specimen diluent provided. Prepare serial two fold dilutions of the human IgM 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:

Anti-Human IgM coated microwell strips 12x8 with plastic frame
HRP conjugated goat anti-human IgM -12mL
IgM standard (pre-diluted 1:10,000)
TMB/peroxide substrate color developer -12mL
IgM specimen diluent (Specimen Diluent Green II) -60mL
Sulfuric acid termination reagent (0.5N) -12mL
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.

Dynamic Range:

0.031mg/mL to 2.0 mg/mL.

Reproducibility:

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

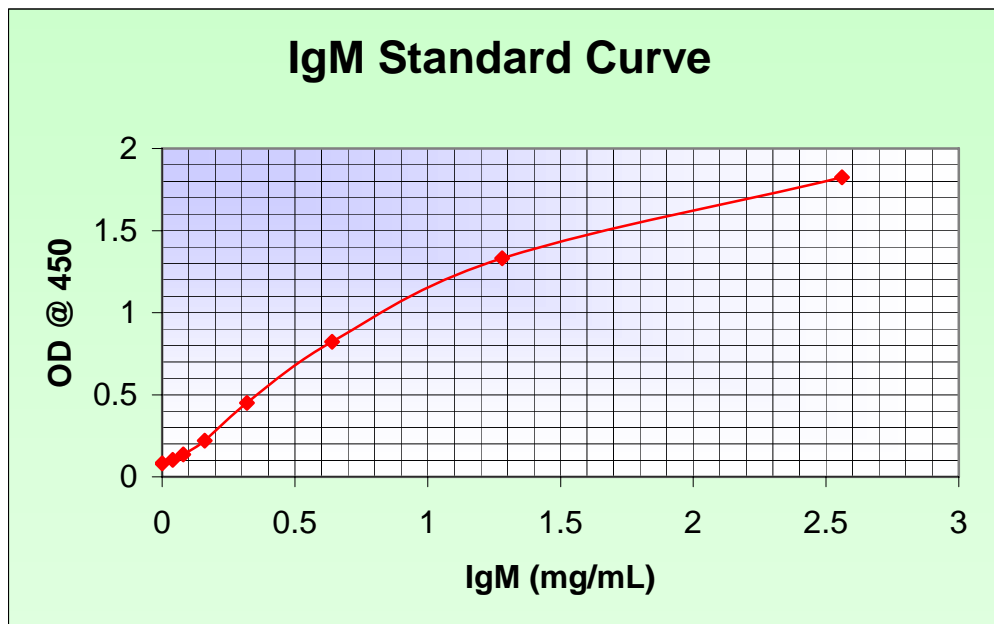
Assay Procedure:

*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 60 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 IgM to each well
5. Incubate at room temperature for 60 minutes
6. Decant and wash as in step 3
7. Add 100uL of TMB/peroxide substrate and incubate at room temperature for 30 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

Typical Standard Curve:



DIAGNOSTIC AUTOMATION, INC.

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

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

ISO 13485-2003

Revision Date: 4/10/06