

# AccuDiag<sup>™</sup> Total Human IgM ELISA Kit

### Cat# 1804-9

See external Label -	rc s'c	$\overline{\mathbb{V}}_{96 \text{ Tests}}$
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Test	Total Human IgM	
Method	Enzyme Linked Immunosorbent Assay	
Principle	Sandwich Complex	
Detection Range	0.031 mg/mL-2.0 mg/mL	
Sample	10 µL Serum/ plasma	
Specificity	94 %	
Sensitivity	0.031 mg/mL	
Total Time	~150 min	
Shelf Life	12-14 Months from the manufacturing date	

### INTENDED USE

To quantitate total human Immunoglobulin M (IgM).

# **TEST PRINCIPLE**

Solid phase capture sandwich ELISA assay using a microwell format.

# Patient and Standard Dilutions:

Dilute each serum or plasma specimen to be tested initially 1:100 with phosphate buffered saline (PBS), then dilute 1:100 in the IgM specimen diluents provided. The final dilution factor will be 1:10,000.

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 AND COMPONENTS

#### Materials provided with the test kits

- 1. Anti-Human IgM coated microwell strips 12x8 with plastic frame
- 2. HRP conjugated goat anti-human IgM -12mL
- 3. IgM standard (pre-diluted) 1 mL (Store at -20 ° C)
- 4. TMB/peroxide substrate color developer –12mL
- 5. IgM specimen diluent (Specimen Diluent Green II) -1 x 60mL
- 6. Sulfuric acid termination reagent (0.5N) -12mL
- 7. 15 X Wash buffer concentrate 60mL

### ASSAY PROCEDURE

\*Caution: All human fluids should be treated as infectious agents that could carry HIV.

\*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.
- 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.

\*Interpolated concentrations greater than 2 mg/mL should be sub diluted 1:4 and re-assayed then corrected mathematically

# LIMITATIONS OF PROCEDURE

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

#### **Dynamic Range:**

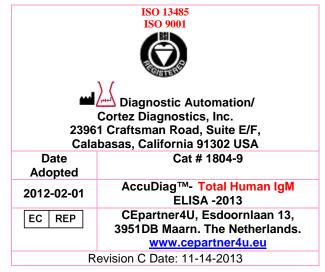
0.031 mg/ml - 2.0 mg/mL

#### **Reproducibility:**

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

### Shelf Life

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



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