Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

CE

AccuDiag™ Total Human IgM ELISA Kit

Cat# 1804-9

IVD See external Label 2°C 8°C Σ 96 Tests

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.
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.

***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°-8°C, except for standard, which should be stored at -20°C.

ISO 13485
ISO 9001

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Date Adopted	Cat # 1804-9
2012-02-01	AccuDiag™- Total Human IgM ELISA -2013
EC REP	CEpartner4U, Esdoornlaan 13, 3951DB Maarn. The Netherlands. www.cepartner4u.eu
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