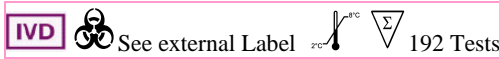


**AccuDiag™
 Human Allergen Specific IgM
 ELISA Kit**

Cat# 1808-9



Test	Human Allergen Specific IgM
Method	Enzyme Linked Immunosorbent Assay
Principle	Sandwich Complex
Detection Range	Class I - Class IV
Sample	10 µL serum / plasma
Specificity	N/A
Sensitivity	N/A
Total Time	~ 150 min.
Shelf Life	12-14 Months from the manufacturing date

INTENDED USE

To quantitate human allergen specific 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 1:10 using the Specimen Diluent provided. e.g. 10ul of specimen into 90 ul Specimen Diluent. Use the Specimen Diluent alone as the Zero or Blank control well.

MATERIALS AND COMPONENTS

Materials provided with the test kits

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

ASSAY PROCEDURE

*Allow each reagent to reach room temperature before use

1. Add 100uL of *diluted* specimen 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 well.

RESULTS

O.D. at 450nm	Class:
0.000-0.250	Class 0 (Negative)
0.250-0.350	Class I (Equivocal)
0.350-0.450	Class II (True Positive)
0.450-0.550	Class III
>0.550	Class IV


LIMITATIONS OF PROCEDURE

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

Shelf Life

The expiration date for the package and each component is stated on the label(s). Store components at 2°-8°C.

**ISO 13485
ISO 9001**



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Date Adopted	Cat # 1808-9
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