



# DIAGNOSTIC AUTOMATION, INC.

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

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

[onestep@rapidtest.com](mailto:onestep@rapidtest.com)

[technicalsupport@rapidtest.com](mailto:technicalsupport@rapidtest.com)

[www.rapidtest.com](http://www.rapidtest.com)

IVD



See external label



2°C-8°C



Σ=96 tests

REF

Cat # 1808-9

# Human Allergen Specific IgM

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<b>Test</b>	<b>Human Allergen Specific IgM</b>
<b>Method</b>	<b>Enzyme Linked Immunosorbent</b>
<b>Principle</b>	<b>Peroxidase – Conjugated ELISA</b>
<b>Detection Range</b>	<b>Class I –Class IV</b>
<b>Sample</b>	<b>10µl serum</b>
<b>Specificity</b>	<b>N/A</b>
<b>Sensitivity</b>	<b>N/A</b>
<b>Total Time</b>	<b>~120</b>
<b>Shelf Life</b>	<b>12-14 months</b>

*\* 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 human allergen specific 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 components at 2°-8°C.

## 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 Supplied

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

## 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

## Interpretation of 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

Date Adopted	Reference No.
2005-09-27	DA-Human Allergen Specific IgM-2009



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**ISO 13485-2003**



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