



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

Cat # 1807-9

Human Allergen Specific IgA ELISA Assay

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Intended Use:

To quantitate human Immunoglobulin A (IgA) specific for common allergens.

Principle of Procedure:

Solid phase capture sandwich ELISA assay using allergen coated microwells

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 1:10 with the Specimen Diluent provided. Use Specimen Diluent alone as a zero control or blank.

Materials Supplied:

Allergen coated microwell strips 12x8 with plastic frame
HRP conjugated goat anti-human IgA -12mL
TMB/peroxide substrate color developer -12mL
IgA specimen diluent (Specimen Diluent Green II) -1 x 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. 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 IgA 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:

<u>O.D. @450nm:</u>	<u>Class:</u>
0.000-0.250	Class 0
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 IgG-2008



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