



## 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 # 1809-9

# Human Allergen Specific IgG

Cat # 1809-9

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

*\* 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 total human Immunoglobulin G (IgG) Specific for Common Allergens

## 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 **1:100 in the Specimen Diluent provided e.g. 10ul of specimen into 990ul of Specimen Diluent.**

## Materials Supplied:

1. 2-Allergen coated microwell strips 12x8 with plastic frame
2. 2-HRP conjugated goat anti-human IgG-12mL
3. TMB/peroxide substrate color developer –12mL
4. IgG specimen diluent -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 45 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 IgG to each well
5. Incubate at room temperature for 45 minutes
6. Decant and wash as in step 3
7. Add 100uL of TMB/peroxide substrate and incubate at room temperature for 15 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. Optical Densities are interpolated into Classes:

<u>O.D.@450nm</u>	<u>Class</u>
0.000-0.250	Class O (Negative)
0.250-0.350	Class I (Equivocal)
0.350-0.450	Class II
0.450-0.550	Class III
>0.550	Class IV

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



**DIAGNOSTIC AUTOMATION, INC.**

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

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

**ISO 13485-2003**



Revision Date: 10/10/2009