



## DIAGNOSTIC AUTOMATION, INC.

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IVD



See external label



2°C-8°C



Σ=96 tests

REF

Cat # 1805-9

# Human Allergen Specific IgE ELISA Assay

Cat # 1805-9

### Intended Use:

To qualitate and quantitate allergen specific human Immunoglobulin E

\*Note: Prior to running allergen specific IgE assays, be sure to determine the total IgE of the specimen.

### 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 all components at 2°-8° C. Do not freeze all or in part.

### Materials Supplied:

Allergen coated microwell strips 12x8 with plastic frame –2

HRP conjugated goat monoclonal anti-human IgE -2-12mL

TMB/peroxide substrate color developer II -30mL

Sulfuric acid termination reagent (0.5N) –1-24mL

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 invitro diagnostic use.

## Dynamic Range:

0.35 – 0.70 PRU/mL, depending on the type of allergen used.

## Reproducibility:

C.V. 6%-10%

## Assay Procedure:

**\*Caution:** All human fluids should be treated as infectious agents that could carry HIV.

For each specimen, place one strip of allergen coated microwells in the plastic frame and label the corresponding schematic with the patient's names or ID numbers.

1. Bring all reagents to 25°C.
2. Add 100 uL of serum or plasma to each microwell.
3. Incubate for 2 hours at 25°C but not greater than 30°C.
4. Decant and wash five times with previously diluted wash buffer (See “preparation of reagents”.) Firmly grip and pound the microwells upside down on folded, clean paper towels to remove all residual wash buffer after the last wash.
5. Add 100ul of monoclonal Anti-human IgE HRP conjugate to each well.
6. Incubate for two hours as in “step 3”
7. Decant and wash as in “Step 4”.
8. Add 100uL of TMB/peroxide substrate to each well respectively.
9. Incubate for 30 minutes at 25°C but not greater than 30°C.
10. Add 100uL of termination reagent (0.5N sulfuric acid) to each well respectively.
11. Read the optical density (O.D.) at 450 nm using a standard microwell plate reader zeroed on the negative control well.

## Interpretation of FlipSCREEN QAT Results:

0.000 – 0.250 = Negative

0.251 – 0.350 = Class I

0.351 – 0.450 = Class II

0.451 – 0.550 = Class III

> 0.550 = Class IV

## Preparation of Reagents:

### **Wash Buffer:**

Prior to performing the assay, dilute 1 part of the 15X Wash Buffer concentrate in 14 parts of reagent grade water. Mix thoroughly and dispense into a squeeze wash bottle as needed.

<b>Date Adopted</b>	<b>Reference No.</b>
<b>2005-09-27</b>	<b>DA-Human Allergen Specific IgE-2008</b>



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