

AccuDiag™ Human Allergen Specific IgE ELISA Kit

Cat# 1805-9



Test	Human Allergen Specific IgE
Method	Enzyme Linked Immunosorbent Assay
Principle	Sandwich Complex
Detection Range	Class I - Class IV
Sample	100 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 qualitative and quantitative allergen specific human Immunoglobulin E.
*Note: Prior to running allergen specific IgE assays, be sure to determine the total IgE of the specimen.

TEST PRINCIPLE

Solid phase capture sandwich ELISA assay using a microwell format.

REAGENT PREPARATION

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.

MATERIALS AND COMPONENTS

Materials provided with the test kits

- 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). -2-12mL
- 15 X Wash buffer concentrate. -60mL

ASSAY PROCEDURE

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

* Allow each reagent to reach room temperature before use.

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.

- Bring all reagents to 25°C.
- Add 100 µL of serum or plasma to each microwell.
- Incubate for 2 hours at 25°C but not greater than 30°C.
- 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.
- Add 100µl of monoclonal Anti-human IgE HRP conjugate to each well.
- Incubate for two hours as in "step 3"
- Decant and wash as in "Step 4".
- Add 100µL of TMB/peroxide substrate to each well respectively.
- Incubate for 30 minutes at 25°C but not greater than 30°C.
- Add 100µL of termination reagent (0.5N sulfuric acid) to each well respectively.
- Read the optical density (O.D.) at 450 nm using a standard microwell plate reader zeroed on the negative control well.

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

LIMITATIONS OF PROCEDURE

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

Dynamic Range:


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

Reproducibility:

C.V. 6%-10%

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.

<p>ISO 13485 ISO 9001</p>  <p>Diagnostic Automation/ Cortez Diagnostics, Inc. 23961 Craftsman Road, Suite E/F, Calabasas, California 91302 USA</p>	
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