



7018 Owensmouth Ave. Suite 103  
Canoga Park, CA, 91303  
Phone: 818-710-1281  
Fax: 818-936-0121

Email: [Info@immunospec.com](mailto:Info@immunospec.com)  
[www.immunospec.com](http://www.immunospec.com)



## Immunoglobulin E (IgE) Test Disk

For Plasma or Serum

REF

Catalog No. R11-402

IVD

*For In Vitro Diagnostics*

### Explanation of the Test

An immunoglobulin E immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the immunoglobulin E (serum antibodies) in serum/plasma. Measurement of these immunoglobulins aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

The Immunospec's IgE test is a highly sensitive immunoassay for qualitative determination of human IgE in plasma or serum. This test is intended for professional use as an aid in the diagnosis and treatment of IgE-mediated allergic and autoimmune disorders. The sensitivity of the test is 80 IU/ml.

### Materials Provided

The IgE test kit contains the following items to perform the assay.

1. IgE test device.
2. Disposable sample dropper.
3. Instructions for use.

### Precautions

The Immunospec's IgE test kit should be stored at room temperature 4-30°C (40-86°F). The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

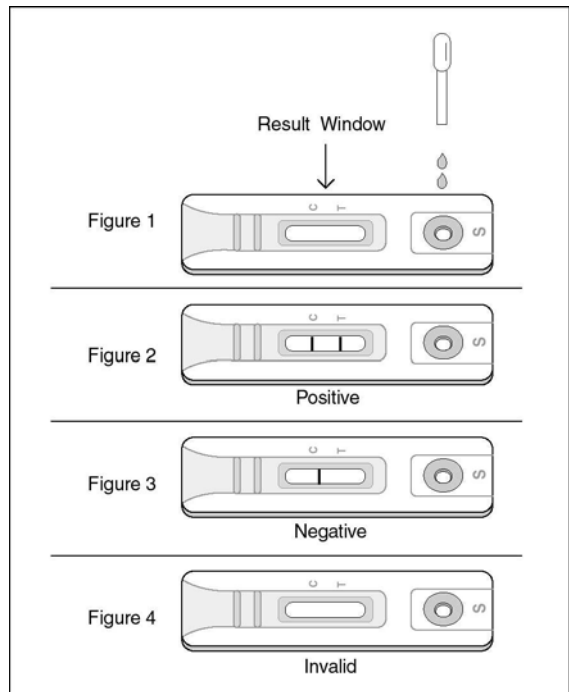
### Specimen Collection and Storage

1. The test may be performed using human plasma or serum.
2. If specimens are not immediately tested they should be refrigerated at 2-8 °C. For storage periods greater than three days, freezing is recommended.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

### Warnings

1. For in vitro diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.

### Procedure of the Test



1. Remove the test disk from the foil pouch, and place it on a flat, dry surface.
2. Holding the sample dropper above the test disk, squeeze 2 drops of specimen into the Sample Well (Figure 1).
3. As the test begins to work, you will see purple color move across the Result Window in the center of the test disk.
4. Interpret test results at 5 minutes. Do not interpret test results after 5 minutes.

**Caution:** The above interpretation time is based on reading the test results at room temperature of 15 to 30 °C. If your room temperature is significantly lower than 15 °C, then the interpretation time should be properly increased.

### Interpretation of the Test

1. A color band will appear at the left section of the result window to show that the test is working properly. This band is the Control Band.
2. The right section of the result window indicates the test results. If another color band appears at the right section of the result window, this band is the Test Band.

**Positive Result:** The presence of two color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result (Figure 2). Note: Generally, the higher the analyte level in the specimen, the stronger the "T" band color will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the color of the "T" band will be very faint.

**Negative Result:** The presence of only one purple color band within the result window indicates a negative result (Figure 3).

**Invalid Result:** After performing the test and no purple color band is visible within the result window, this result is considered invalid. The direction may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be tested again (Figure 4).

*Note: A positive result will not change once you have established your answer at 5 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after 5 minutes. Interpreting test results after 5 minutes, the sensitivity of the test will be higher than 80 IU/ml. Some serum specimens with a high rheumatoid factor concentration may yield a nonspecific positive result.*

### Limitations of the Test

Although the Immunospec's IgE Test is very accurate in detecting IgE, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

### Specificity

An in-house study is conducted with 3 separate lots of the Immunospec's IgE Serum, plasma or whole blood Test to determine the Specificity of the Immunospec's IgE test. Samples included: Serum with triglyceride concentrations up

to 500 mg/ml, Serum with Bilirubin concentrations up to 10 mg/100ml, Hemolyzed specimens with hemoglobin concentrations up to 10 mg/ml, Prostatic acid phosphatase with concentrations up to 1000 ng/ml and Albumin with concentrations up to 20 mg/ml.

All of the above were analyzed and did not show interference or cross reactivity with the test.

#### References

1. Hamilton RG and Adkinson MF, "Clinical Laboratory Methods for the Assessment and Management of Human Allergic Diseases," *Clin Lab Med*, 1986, 6:117-38.
2. Jeske DJ and Capra JD, "Immunoglobulins: Structure and Function," *Fundamental Immunology*, Paul WE, ed, New York, NY: Raven Press, 1984, 131-65.
3. Ownby DR, "Allergy Testing: *In Vitro* Versus *In Vivo*," *Pediatr Clin North Am*, 1988, 35:995-1009.
4. Van Arsdel PP Jr and Larson EB, "Diagnostic Tests for Patients With Suspected Allergic Disease," *Ann Intern Med*, 1989, 110(4):304-12.
5. Wall R and Kuehl M, "Biosynthesis and Regulation of Immunoglobulins," *Annu Rev Immunol*, 1983, 1:393-422.

EC

REP

#### European Authorized Representative:

CEpartner4U, Esdoornlaan 13, 3951DB Maarn  
. The Netherlands. Tel.: +31 (0)6.516.536.26



#### Manufacturer:

IMMUNOSPEC CORPORATION  
7018 Owensmouth Ave. Suite # 103  
Canoga Park, C.A. 91303 USA  
(818)-710-1281

PIR11-402  
Revision Date: 03/10/2005  
Revision #: 1