

CORTEZ DIAGNOSTICS, INC.

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See external label



2°C-30°C



Σ=25 or 50 tests



Cat. #15150-1

IgE Serum Test

Cat # 15150-1

AN IMMUNOSSAY TEST KIT FOR DETERMINATION OF ELEVATED TOTAL-IgE LEVELS IN HUMAN SERUM

INTENDED USE

The Cortez Diagnostic Inc. Total-IgE Test is a qualitative immunoassay for the detection of elevated levels of immunoglobulin E (total IgE) in human serum or plasma. The immunochromatographic "sandwich" detection method employs a unique combination of monoclonal and polyclonal antibodies against human IgE that allows the detection of elevated serum IgE levels in five minutes.

SUMMARY AND EXPLANATION OF THE TEST

An elevated concentration of IgE in serum is a common symptom associated with allergic pathologies; it may also be caused by autoimmune diseases and some infections.¹⁻³ Rapid detection of elevated levels of IgE using the Cortez Total-IgE Test will help in the diagnosis and treatment of IgE-mediated allergic and autoimmune disorders.

The Cortez Total-IgE Test is an immunochromatographic assay which utilizes immobilized and dye-conjugated monoclonal and polyclonal antibodies against human IgE to selectively identify elevated IgE levels with a high degree of sensitivity.

PRINCIPLE OF THE TEST

The test utilizes the "sandwich" immunodetection principle. Dye-conjugated polyclonal antibody against human IgE and immobilized mouse monoclonal anti-human IgE antibody bind to IgE in the sample specimen to produce a distinctive visual pattern registering IgE concentrations of 80 IU/ml and higher. In the test procedure, patient serum or plasma is added to the sample well "S" of the test device with the aid of a sample dropper. Labeled antibody-dye conjugate binds to the human IgE molecules present in the specimen forming an antigen-antibody-dye complex. When the total IgE concentration is at or above the sensitivity level of the test, a visual test band forms in the test zone "T" as immobilized antibody captures the IgE-dye complex and forms an antibody-

antigen-antibody-dye "sandwich." Proper test performance is verified by a visible control band which forms as immobilized reagents in the control zone capture free dye conjugate in the migrating solution. A pink-rose band in the control zone "C" indicates the test is functioning properly.

REAGENTS AND MATERIALS PROVIDED

1. Testing Device. Cat. # 12050
2. Sample Dropper. A dropper is sealed in each foil pouch with the Testing Device. Cat. # PIP-003
3. Test Instructions. Cat. # PI-12050

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container.
2. Clock or timer.
3. Centrifuge capable of 1,000 g centrifugal force (for centrifugation of whole blood specimens).

STORAGE AND STABILITY

Store the kit below 28°C; do not freeze. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. When handling serum, preclude any pipetting by mouth.
2. Do not allow smoking or eating where the specimens are being handled.
3. Wear disposable gloves while handling kit reagents or specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Wipe up spills thoroughly using an appropriate intermediate-to-high level disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials as if they were infectious in a biohazard container.
7. Do not use the kit or reagents after the expiration date.
8. For in vitro diagnostic use only.

SAMPLE COLLECTION AND PREPARATION

Collect blood aseptically by venipuncture into a clean tube without anticoagulants. Permit blood to clot for twenty to thirty minutes at room temperature. Centrifuge to obtain clear serum and transfer serum into a clean plastic or glass tube. The test may be performed using human serum or plasma.

If specimens are not immediately tested they should be refrigerated at 2° -8° C. For storage periods greater than three days, freezing is recommended (-20°C). If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

TEST PROCEDURE

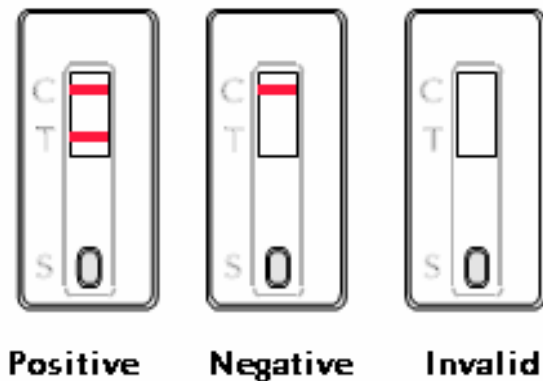
NOTE: Bring an unopened foil pouch and the sample specimen to room temperature before performing the test.

1. Open the foil pouch by tearing at the notch and remove the test device and

dropper.

2. Holding the dropper vertically, add four drops of serum or plasma directly to the sample well "S" of the test device.
3. Read the result at five minutes.
Important: Discard the test device after reading the result. Do not interpret the result after more than five minutes.

INTERPRETATION OF RESULTS



1. **Positive.** A rose-pink color band appears in the Control Zone "C" and in the Test Zone "T." A positive result indicates that the total IgE concentration in the sample is 80 IU/ml or higher.
2. **Negative.** A rose-pink color band appears in the Control Zone "C", and no band is visible in the Test Zone "T". A negative result indicates that the IgE concentration in the sample is below the detection sensitivity of 80 IU/ml.
3. **Invalid.** No color band appears in the Control Zone or a color band appears only in the Test Zone. The test should be considered invalid and it is recommended that the specimen be retested.

Note: *There is no meaning attributed to line color intensity or width.*

LIMITATIONS OF THE TEST

1. The Cortez Total-IgE Test is limited to the qualitative determination of total IgE in serum, plasma, or recalcified plasma.
2. The test is for in vitro diagnostic use only.
3. Although the Cortez Total-IgE Test is very accurate in detecting elevated IgE levels, a low incidence of false results can occur.
4. 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.

PERFORMANCE CHARACTERISTICS

1. Specificity and Sensitivity

An evaluation of the Cortez IgE Test was performed to determine the clinical performance in comparison to another commercially available IgE ELISA test kit. A total of 25 patients were included in the study. The results of the study were as follows:

Cortez IgE Test/ELISA

+/+ 14	+/1 1
1/- 0	-/- 9

In conclusion, as shown above, the Cortez IgE test demonstrated 100% relative sensitivity and 90% relative specificity when comparing to the IgE ELISA test kit. By using the 80 IU/ml as the cut-off reading, one patient defines a weak positive while the ELISA assay value was interpreted at 75 IU/ml. The clinical significance of the two tests is comparable.

2. Precision

A. Intra-Assay

Within-run precision was determined by testing 3 lots of Cortez IgE Test with negative, cut-off and positive controls. The negative, cut-off and positive results were correctly identified 100% of the time.

B. Inter-Assay

Between-run precision was determined using 3 different lots of controls. Again, the negative, cut-off and positive findings were correct 100% of the time.

BIBLIOGRAPHY

1. Raikow, R.B., Tyutyunikov, A., Kennerdels, J.S., Kazim, M., Daibow, M.H., and Deborah, S. Ophthalmology, 99: 361-365 (1992).
2. Williams, P.B., Dolen, W.K., Koepke, J.W., and Seiner, J.C. Annals of Allergy, 68: 35-45 (1992).
3. Michaels, D.L. Annals of Allergy, 67: 425-428 (1991).

Date Adopted	Reference No.
2005-09-27	DA-Total IgE-2008



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