Total IgE

infinosis™

Immunoglobulin E Total (FIA)

REF: IN067705 Σ 25

Intended use
The infinosis™ Total IgE is a fluorescence-based lateral flow assay for the in vitro quantitative determination of Immunoglobulin E total in Human whole blood, serum or plasma. For professional use only.

Summary
References[1-7]
Indications: allergic diseases, helminthiasis, eczematous or non eczematous dermatitis, IgE myeloma, etc. Diagnosis of allergic reactions and atopic diseases: in addition to skin and provocation tests and detection of specific IgE, the diagnosis of allergic diseasesalso includes detection of total IgE level. However, allergic reactions were not always accompanied by an increase in total IgE levels (adults > 100 IU/ml). On the contrary, low levels of IgE (adult < 25 IU/ml) can not rule out allergic reaction. Through long-term desensitization treatment and keeping away from allergens, the total IgE titer usually decreases.By measuring the total IgE level, allergic asthma and endogenous asthma, allergic rhinitis and vasomotor rhinitis, as well as infant atopic dermatitis and seborrheic dermatitis can be distinguished. High concentrations of IgE (thousands of IU/mL) were found in patients with atopic dermatitis. Other allergic (and high IgE) diseases include acute recurrent or chronic urticaria, recurrent Quincke edema (angioneurotic edema), gastrointestinal intolerance, and rashes of unknown origin. Detection of total IgE can also be used in the differential diagnosis of pulmonary eosinophilic infiltration, allergic aspergillosis, exogenous allergic alveolitis (farmer's lung and pigeon's lung) and church strau β syndrome.IgE in other diseases: non allergic diseases with high IgE levels include various forms of helminthiasis, such as toxocariasis, ascariasis, schistosomiasis, hookworm disease, leishmaniasis and trichonematodiasis. However, no increase of IgE level was found in taeniasis and enterobiasis. For most cases, after effective treatment, IgE level can be reduced to normal range. High concentrations of IgE can be detected in the following diseases: eczematous or non eczematous dermatitis, IgE myeloma, Acute systemic lupus erythematosus (SLE), Graft versus host response, T cell defect (Wiskott Aldrich syndrome), second or third degree burns, Otorhinolaryngological tumors, Liver disease (especially related to alcohol abuse), Late stage of AIDS (CD4 + T cells decreased significantly) IgE deficiency may occur in the following diseases: x-chromosome-related hypogammaglobulinemia, Severe combined immunodeficiency (SCID), and Pulmonary fibrosis disease.

Test principle
Sandwich principle. Total duration of assay: **15 minutes**
Sample is added to the sample well of the test, then the fluorescence-labeled detector anti-Total IgE antibody binds to Total IgE antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and Total IgE are captured to anti-Total IgE antibody that has been immobilized on test strip. The more Total IgE antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of Total IgE captured and instrument for infinosis™ tests shows Total IgE concentrations in blood specimen.

Reagents
Materials provided
- **Test Cartridge**, 25 pcs, individually packaged
- **ID Chip**, 1 pcs
- **Sample Buffer,** 25 vials
- **IFU**, 1 copy

Materials required (but not provided)
- infinosis™ 2020 FIA analyzer
- Total IgE control (DiaSino control is recommended)
- Transfer pipette set (100 μL size)
- Centrifuge (for plasma and serum only)
- Timer

Precautions and warnings
- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this instructions before testing.
- The test cartridge should remain in its original sealed pouch until ready to use. Do not use it if the pouch is damaged or the seal is broken.
- Do not use reagents beyond the labeled expiry date.
- Do not mix or use components from kits with different Lots.
- Don't use Test Cartridge if its Lot does not match with ID Chip that is inserted onto the instrument.
- The infinosis™ Total IgE should be used only in conjunction with the instrument for infinosis™ tests.
- The tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample is taken by qualified medical personnel.
- infinosis™ Total IgE assay is single use only. Do not reuse it.
- The Test Cartridge and instrument for infinosis™ tests should be used away from vibration and magnetic field. During normal usage, the Test Cartridge may generate slight vibration, which should be regarded as normal.
- Use separate clean pipette tips and buffer tubes for different specimens. The pipette tips and detector buffer tubes should be used for one specimen only.
- Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
- Blood specimens, used test cartridges, pipette tips and sample buffer tubes are potentially infectious. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
- The results should be interpreted by the physician along with clinical findings and other laboratory test results.

Incident report
Any suspected serious incidents related to this assay shall be immediately reported to DiaSino, DiaSino's Authorized Representative in the EU, and the national competent authorities of the Member States where the users and/or patients are located.

Storage and stability
- Store the test kit at 2-30℃, the stability is up to the expiration date printed on package.
- Test cartridge and sample buffer should be used within 1 hour after opening the pack.

Specimen collection and preparation
- The test can be performed with either whole blood, serum or plasma.
- Collect serum samples in accordance with correct medical practices.
- Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
- Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
- Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

Quality control
- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with infinosis™ tests. For more information regarding obtaining the control materials, contact DiaSino Laboratories Co., Ltd for assistance.

Test setup
- Ensure that the lot number of the cartridge matches that of the sample buffer, and the ID Chip.
- If the sealed cartridge and sample buffer have been stored in refrigerator, place them at room temperature (18-25 ℃) at least 30 minutes before measurement.
- Turn on the instrument for infinosis™ tests.

Test procedure
1. Insert ID Chip into the instrument for infinosis™ tests and read ID chip information.
2. Using a pipette to transfer **50 μL** of sample (Human plasma/serum/whole blood) to the **sample buffer tube** provided in the kit.

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3. Close the lid of the sample mixing tube and mix the sample thoroughly for **5-10 seconds** by tapping or inverting the tube.
4. Pipette out **100 µL** of **sample mixture** and load it onto the sample well on the cartridge.
5. Leave the sample-loaded cartridge at room temperature for **15 minutes.**
6. Insert the sample-loaded cartridge into the cartridge holder of instrument for infinosis™ tests.
   Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder.
7. Press **"Test"** button on the instrument for infinosis™ tests.
8. Instrument for infinosis™ tests will start scanning the sample-loaded cartridge immediately.
9. Read the test result on the display screen of the instrument for infinosis™ tests.
10. Print out the testing results when press **"Print"** button on the instrument for infinosis™ tests.

Limitations - interference

- The assay is unaffected by icterus (bilirubin < 1112 µmol/L or < 65 mg/dL), hemolysis (Hb < 0.31 mmol/L or < 0.5 g/dL), lipemia (Intralipid < 3300 mg/dL) and biotin (< 205 nmol/L or < 50 ng/mL).
- Criterion: Recovery within ± 10 % of initial value.
- Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.
- No interference was observed from rheumatoid factors up to a concentration of 2500 IU/mL.
- There is no high-dose hook effect at Total IgE concentrations of up to 50000 µg/L (ng/mL).
- Iron2+- and iron3+-ions at therapeutic concentrations do not interfere with the DiaSino Total IgE assay.
- In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Measuring range

7.0-1000 IU/mL (defined by the lower detection limit and the maximum of the master curve). Values below the lower detection limit are reported as < 7.0 IU/mL. Values above the measuring range are reported as > 1000 IU/mL.

Lower detection limit

7.0 IU/mL

The detection limit represents the lowest analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (master calibrator, standard 1+2 SD, repeatability study, n = 21).

Expected values

Age	Normal range, IU/mL
Newborns	< 1.4
1-6 months	< 7.5
7-12 months	< 13
1-5 years old	< 58
6-9 years old	< 167
10-15 years old	< 202
> 16 years old	< 97

Expected values may vary with age, sex, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practice.

Specific performance data

Representative performance data are given below. Results obtained in individual laboratories may differ.

Intra-assay precision	:	5.8%
Inter-assay precision	:	6.5%
Inter-lot precision	:	6.7-7.5%
Analytical sensitivity	:	7.5 IU/mL
Recovery	:	87-97%
Linearity	:	95-125%
Cross-reactivity	:	No cross-reactivity to Immunoglobulin G
Interferences	:	No interferences to bilirubin up to 0.3 mg/mL, hemoglobin up to 8.0 mg/mL and triglycerides up to 5.0 mg/mL
Clinical specificity	:	100%
Clinical sensitivity	:	100%

Method comparison

A comparison of the Infinosis™ Total IgE assay (y) with the Roche Elecsys Total IgE assay (x) using 79 clinical samples gave the correlation: r=0.9512

References

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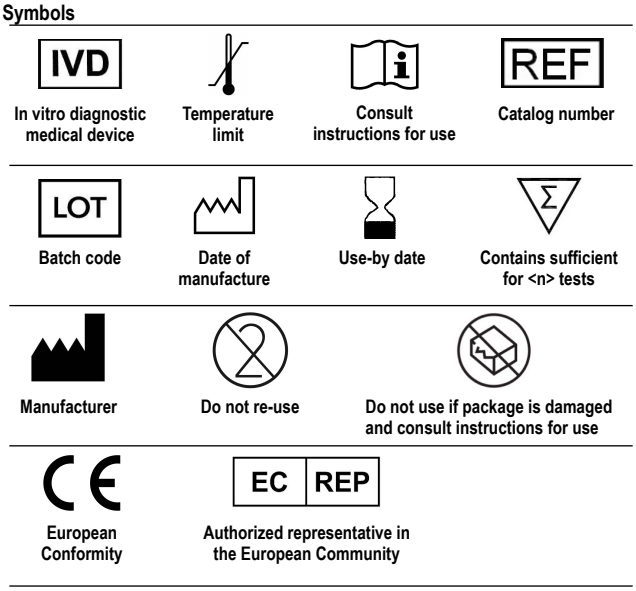
6. Barbee RA, Halonen M, Kaltenborn W, Lebowitz M, Burrows B. A longitudinal study of serum IgE in a community cohort: Correlations with age, sex, smoking, and atopic status. J Allergy Clin Immunol; 79: 919-927 (1987)
7. Elkayam O, Tamir R, Pick AI, Wysenbeek A. Serum IgE concentrations, disease activity, and atopic disorders in systemic lupus erythematosus. Allergy; 50: 94-96 (1995)

Symbols



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