CE IVD 2°C 8°C DR FOOKE

Please read instructions for use carefully before performing the assay

ALFA Total IgE

Lateral Flow Assay for the qualitative determination of Total IgE in human serum or plasma

REF 183000 Σ 20

BACKGROUND

Allergic reactions of the immediate type (type I allergies) are mediated by allergen specific Immunoglobulin of class E. The normal serum IgE concentration is age dependent with a peak at the age of 6-15 years. The occurrence of allergen specific IgE is often accompanied by increased titres of total IgE in the blood of the patients. In these cases the titre can increase up to 1000fold. Usually, IgE concentrations are determined in international units per millilitre (IU/mL) whereat 1 IU/mL corresponds to 2.4 ng of IgE. Highest IgE concentrations occur in patients with atopic dermatitis in which they often reach levels of 50.000 IU/mL. Moreover, increased titres of IgE can be observed in patients with parasitic diseases. Deviations to the normal values have also been described in patients with certain autoimmune disorders.

INTENDED USE

ALFA (**A**llergy **L**ateral **F**low **A**ssay) Total IgE is a rapid assay for the qualitative determination of total IgE in human serum, plasma or whole blood.

PRINCIPLE

ALFA Total IgE consists of a test device – the ALFA Total IgE *Basis Set* – in combination with an *Anti-IgE Solution*.

To perform the test the patient's sample is transferred to the sample application point of the *Basis Set*. Immediately afterwards the *Anti-IgE Solution* is applied. During incubation time of 25-30 min the liquid is driven through the device by capillary flow. Anti-IgE binds specifically to IgE antibodies of the sample. The anti-IgE is labelled and is retained at the test line (T) by a capture molecule. At the same time, patients IgE bound to anti-IgE is bound by an antibody coupled to coloured particles (conjugate). The intensity of the colour-reaction of the three test lines is proportional to the amount of immune complexes consisting of ligand tagged anti-IgE, IgE, and IgE specific conjugate. For interpretation of the result, the number of visible test lines and their intensity is assessed by an evaluation card.

Access conjugate which is not bound at the test line forms a dark-ruby control line (C) after 25-30 min of incubation.

KIT COMPONENTS

ALFA Total IgE *Basis Set*:	Basis Set (ready to use) for the detection of total IgE 20 test units = 20 determinations
ALFA Anti-IgE Solution:	Ready to use
Evaluation Card:	For assessment of the result
Order number:	183000
Storage:	At 2-8°C, do not freeze! Use Basis Set immediately after opening the foil pouch!
Shelf life:	To expiry date if stored according to the instructions

MATERIAL NEEDED BUT NOT PROVIED

- micro pipette and pipette tips for 10-20 µL
- tubes for serum preparation if required

SPECIMEN COLLECTION & PREPARATION

Serum, plasma or whole blood can be used with this assay. The use of haemolytic or lipemic specimens must be avoided. No additives or preservatives are necessary to maintain the integrity of the specimens if stored at 2-8°C and assayed within 48 hours after collection. If this is not possible or if specimens have to be shipped, samples must be frozen. To perform the assay, thaw and bring samples up to room temperature (RT, 18-25°C). Repeated freezing and thawing should be avoided.

ASSAY PROCEDURE

Attention!

Bring *Basis Set* (in foil pouch) as well as the *Anti-IgE Solution* up to RT, at least 30 min before performing the assay.

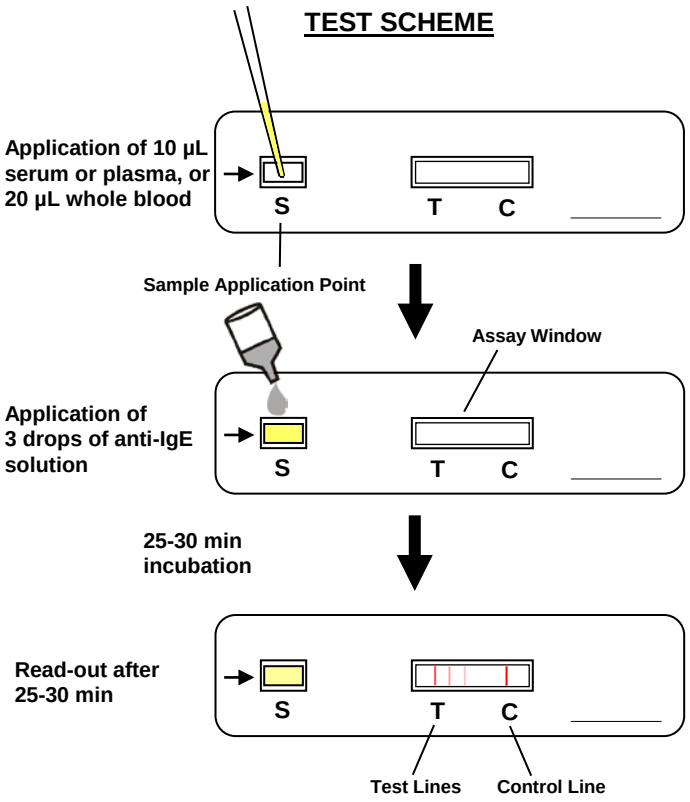
- If the foil pouch is damaged do not use the test unit.
- Use the test unit within 30 min after opening the foil pouch.
- Avoid performing the test in direct sunlight.
- Avoid movement of the cassette while running the assay.

1. Transfer **10 µL of serum or plasma, or 20 µL whole blood** to the sample application point of the *Basis Set*.

2. Immediately afterwards apply **3 drops** of the desired **Anti-IgE Solution** to the sample application point of the *Basis Set*.

3. The test result will be visible in the evaluation window after 25-30 minutes of incubation.

The test result has to be interpreted within 25 to 30 min after starting the assay. Any assessment which is done later or earlier can cause erroneous interpretation of the result!



INTERPRETATION OF THE RESULTS

Attention! The test result is only valid if the control line (C) of the test unit is clearly visible.

The results of ALFA Total IgE have to be evaluated based on the number of visible test lines (T) and their intensities by an evaluation card delivered with this assay.

Attention should be drawn to:

- For the experienced user assessment in IU/mL is possible. However, assessment of the results in the given classes is recommended.
- Weak signals may become visible not before 25-30 min of incubation.
- Strong positive results may become visible before 25-30 min of incubation.
- The colour of the control line is usually more intensive than of the test lines.
- Sample with very high titres of total IgE (> 5000 IU/mL) can lead to undervalued results (*high-dose-hook-effect*).

With the aid of the LFA Reader (REF 190001 or 190002) the test result can be interpreted semi-quantitatively in U/mL. The measurement has to be performed according to the instruction for use of the LFA Reader.

PERFORMANCE

Correlation of ALFA Total IgE to Reference-Method

Chi-square (χ^2) between ALFA Total IgE and results of the CE-labeled Total IgE HRP EIA (08102CP) of Dr. Fooke Laboratorien GmbH is 58.3.

Reproducibility of ALFA Total IgE

Chi-square (χ^2) between results of two observers is 29.9. Inter-Assay Variation in % is 16.

MEASURING RANGE

The measuring range of ALFA Total IgE is defined by the provided evaluation card and ranges from 5 IU/mL to 1000 IU/mL.

DETECTION LIMIT

The detection limit of ALFA Total IgE is 5 IU/mL. The buffer control gives no false positive results.

EXPECTED VALUES

Before clinical assessment of the results, every laboratory should establish its own age-related normal range by using appropriate statistics over a relevant time span and with relevant patient number. The results[(1)] below can be used as a guideline.

Age (years)	n	Mean (IU/mL)	Mean + 1 SD (IU/mL)
1-2	29	20	64
3-5	31	35	119
6-15	45	51	150
16-20	59	38	123
21-30	114	27	100
31-40	38	34	113
>40	109	34	114
total	425	32	108

SD = Standard Deviation

LITERATURE

1. Wittig H, Bellot J, Fillippi I, Royal G. **Age-related Serum IgE Levels in Healthy Subjects and in Patients with Allergic Disease.** *J Allergy Clin Immunol* 1980, **66**:305-313.

2. Lucassen R, Mahler M, Fooke M. **Development and evaluation of a new rapid assay for semi-quantitative detection of total IgE in human serum and cappilary blood.** Abstract: EAACI 2008 Barcelona, Spain.

PRECAUTIONS FOR USERS

1. In compliance with article 1 paragraph 2b European directive 98/79/EC the use of *in-vitro* diagnostic medical devices is intended to secure suitability, performance and safety of the product by the manufacturer. Therefore the test procedure, information, precautions and warnings stated in the instructions for use have to be followed strictly. The kit has only to be used as described on page 1 (intended use).
2. The test must be performed according to this instruction, which contains all necessary information, precautions and warnings. The use of the test kit with analyzers and similar equipment has to be validated. Any change in design, composition of the test procedure as well as for any use in combination with other products not approved by the manufacturer is not authorized; the user himself is responsible for such changes resulting in false results and other incidents.
3. The kit is intended for use by trained and qualified professionals carrying out research or diagnostic activities only. Pregnant women should not perform the test.
4. Laboratory equipment has to be maintained according to the manufacturer's instructions and must be tested for its correct function before use.
5. For *in-vitro* diagnostic use only. Use only once. Do not use components exceeding the expiry date. Do not combine reagents of other suppliers or kit components of different lots (unless specified on page 1) with this kit.
6. Do not use kit components when the package of the component is damaged. Cap vials tightly immediately after use to avoid evaporation and microbiological contamination. Do not interchange screw caps of the reagent vials.
7. Test components based on human serum were tested using a CE marked method for the presence of antibodies against HIV 1 / HIV 2, Anti-HBc, and Anti-HCV as well as for hepatitis antigen HBsAg and were found to be negative. Nevertheless, material based on human serum should be handled as potentially infectious (BIOHAZARD).
8. Some kit components may contain bovine serum albumin, of which according to the manufacturer no infectious potential is known. Due to the eventual occurrence of undetectable infectious agents we recommend to handle any product of animal origin as potentially infectious.
9. The following safety rules should be followed with all reagents:
   - Do not get in eyes, on skin, or on clothing (P262). Do not breathe spray (P260).
   - IF SWALLOWED: rinse mouth. Do NOT induce vomiting (P301/330/331)
   - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower (P303/361/353).
   - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing (P303/340).
   - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. (P305/351/338)
   - Don't eat, drink or smoke while performing the test. Keep away from food, feed and beverage.
   - Wear protective gloves/protective clothing/eye protection (P280). Wash hands thoroughly after handling (P264) and care for your skin.
10. The preservatives (Bronidix L, Azid) are toxic to aquatic life, but their concentration is not hazardous to environment anymore. On disposal, flush large volumes of reagents with plenty of water.
11. Waste containing serum must be collected in separate containers containing an appropriate disinfectant in sufficient concentration. This material has to be treated according to national biohazard and safety guidelines or regulations.
12. We refer to the national regulations of medical devices regarding *in-vitro* diagnostic test kits.

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Lot- Number	European conformity	For *in-vitro* diagnostic use	Temperature Limit	Use before	Catalogue Number	Consult instructions for use	Refer accompanying documents	Do not use when package is damaged	Do not Re-use	Sufficient for <n> tests	Manu-factured by	Bio-hazard