



ALFA Total IgE

Rapid Assay for the Determination of Total IgE in human Serum, Plasma or Whole Blood

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 titers of total IgE in the blood of the patients. In these cases the titer 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 titers of IgE can be observed e.g. in patients with parasitic diseases. Deviations to the normal values have also been described in patients with certain autoimmune disorders

Intended Use

ALFA (Allergy Lateral Flow Assay) Total IgE is a rapid assay for the qualitative determination of total IgE in human serum, plasma or whole blood. ALFA Total IgE is designed as a screening test which allows a fast and easy detection of increased and highly increased Total IgE titers. Furthermore the test can be used in laboratories as validity check and confirmatory test, respectively.

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

Principle

Immediately after application of the sample (serum, plasma or whole blood) onto the sample application point of the Basis Set, the Anti-IgE Solution is applied. After 25-30 min the result of the test line (T) can be assessed by the help of an evaluation card. The functionality of the test is determined by the control line (C).

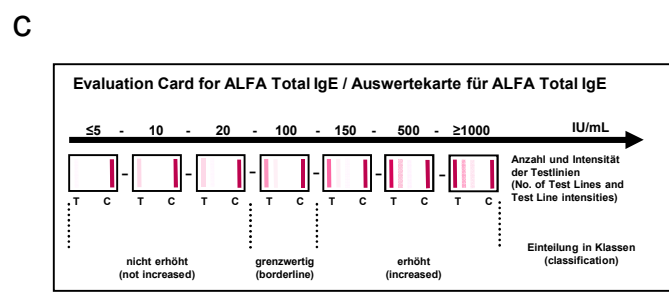
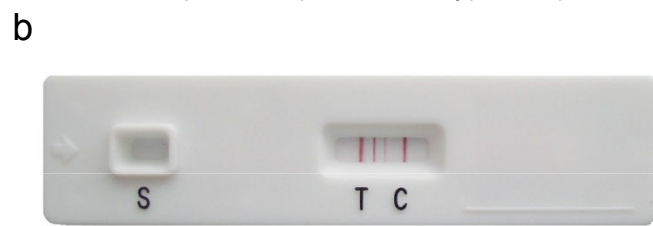
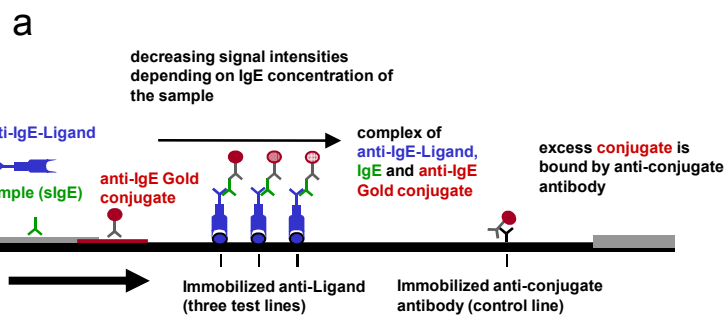


Figure 1
a) Principle of ALFA Total IgE, b) Test Cassette, c) ALFA Total IgE Evaluation Card.



Specifications

- short assay time (result after 25 - 30 min)
- serum, plasma or whole blood can be used
- very good correlation to Total IgE EIA (08102CP)

Agreement to Total IgE EIA

Very good agreement between ALFA Total IgE and Total IgE EIA (Pearson's correlation = 0.931).

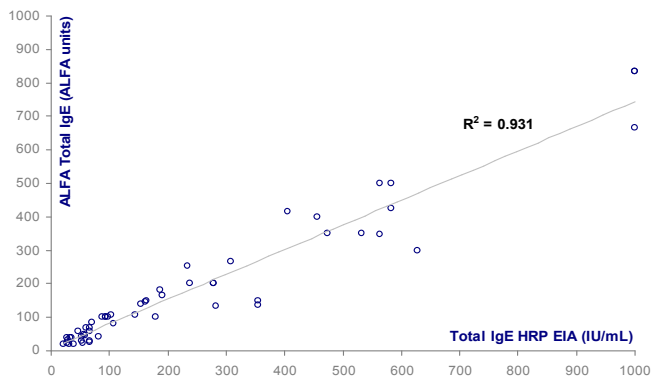


Figure 2
Pearson's correlation (mean of three observers) between ALFA Total IgE and Total IgE ELISA.

Reproducibility of ALFA Total IgE

Data on the reproducibility of ALFA Total IgE is shown in Table 1.

sample ID	IU/mL Total IgE	ALFA Total IgE VB1				ALFA Total IgE VB2				ALFA Total IgE VB3				Mean CV%
		Assay 1	Assay 2	Assay 3	CV%	Assay 1	Assay 2	Assay 3	CV%	Assay 1	Assay 2	Assay 3	CV%	
1	21	20	20	20	0	20	20	20	0	20	20	20	0	0
2	54	35	35	50	18	50	50	50	0	35	50	50	16	11
3	104	100	100	100	0	100	100	100	0	100	150	100	20	7
4	145	100	150	150	18	150	150	150	0	150	150	100	18	12
5	188	150	200	200	13	200	200	200	0	200	150	200	13	9
6	1000	1000	1000	1000	0	1000	500	1000	28	1000	500	1000	28	19

Table 1

Reproducibility of ALFA Total IgE results (IU/mL, Inter-Assay/ Inter-Batch variation)

Literature

1. Ishizaka K, Ishizaka T, and Hornbrook MM: **Physicochemical Properties of Human Reaginic Antibody IV. Presence of a Unique Immunoglobulin as a Carrier of Reaginic Activity.** *J Immunol* 1966, **97**:75-85
2. Wittig H, Bellot J, Fillippi I, and Royal G: **Age-related Serum IgE Levels in Healthy Subjects and in Patients with Allergic Disease.** *J Allergy Clin Immunol* 1980, **66**:305-313
3. 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 capillary blood.** 27th Congress of the European Academy of Allergology and Clinical Immunology held in Barcelona, Spain 2008.

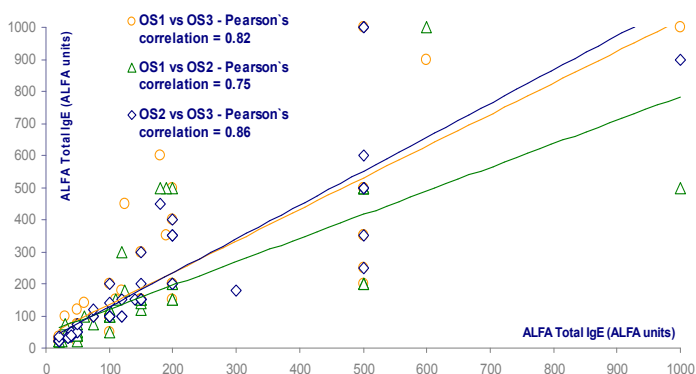


Figure 3
Pearson's correlation of ALFA Total IgE results between observer (OS) 1, 2 and 3.