



ALFA (Allergy Lateral Flow Assay)

Rapid test for the qualitative determination of sIgE in whole blood, serum or plasma

ALFA single strip cassette **REF** 1800010 ∇ 20

ALFA eight strip cassette **REF** 184000 ∇ 80

Background

The worldwide frequency of allergies has increased significantly over the past decades. The term allergy is often used for type I hypersensitivity reactions (immediate type reactions), whose symptoms generally occur within 30-60 minutes after contact with the allergen. The most frequent symptoms are: hay fever (rhinitis), conjunctivitis, hives (urticaria), allergic asthma and as the most dangerous manifestation anaphylaxis (the anaphylactic shock).

The allergens causing type I hypersensitivity reactions are mostly proteins derived from the natural environment e.g. plant pollen, animal hair, food, mites, and insect venoms.

A characteristic of type I allergies is the involvement of allergen specific immunoglobulins (antibodies) of class E (sIgE). Hence, the detection of sIgE is an important tool of modern allergy diagnostics.

Intended use

ALFA (**A**llergy **L**ateral **F**low **A**ssay) is a rapid test for the qualitative determination of allergen specific Immunoglobulin E (sIgE) in human serum, plasma or whole blood.

ALFA consists of a uniform test device - the ALFA *Basis Set* - in combination with several arbitrary single- or allergen-mixture-solutions (screens). Two different test systems are available, a single-strip or an eight-strip cassette.

Test procedure

The sample (serum, plasma or whole blood) is transferred onto the sample application point of the Basis Set. Immediately afterwards the desired allergen solution is added. After 20 minutes the result can be evaluated based on the test line (T).

The functionality of the test is evaluated based on the control line (C).

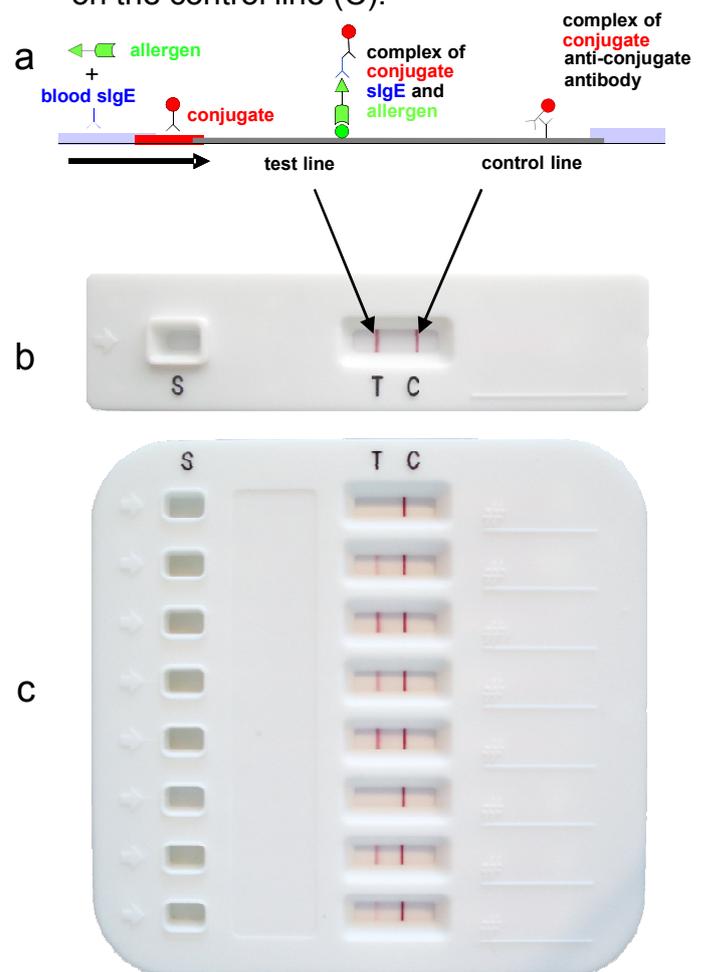


Figure 1

a) Test principle ALFA, b) Positive result (single-strip cassette), c) Different results (eight-strip cassette).



Allergens

By choosing the right allergen solution patient and symptom-specific testing is feasible.

Amongst others the following single-allergens and allergen mixtures are available:

House dust mites (*D. pter.*, d1; *D. farinae*, d2), **Birch** (t3), **Timothy Grass** (g6), **Cat** (e1), **Dog** (e5), ***Alternaria alternata*** (m6).

Seasonal Screen Timothy Grass (g6), *Alternaria alternata* (m6), Birch (t3), Mugwort (w6).

Perennial Screen Mites (*D. pter.*, d1; *D. farinae*, d2), German Cockroach (i6), *Aspergillus fumigatus* (m3).

Further allergens and allergen screens can be found in the current list of ALFA allergens.

Specifications

- Short assay time (result within 20 min)
- Serum, plasma or whole blood applicable
- Excellent correlation with skin prick test and other *in-vitro* sIgE test methods

Performance against skin prick test

The concordance between ALFA and skin prick test is shown in figure 2.

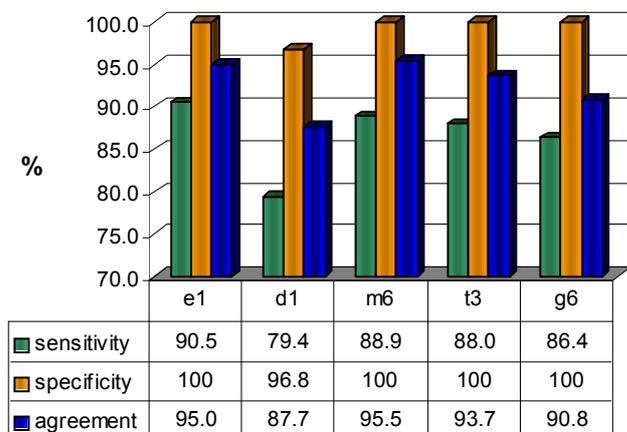


Figure 2
Sensitivity, specificity and agreement of ALFA against skin prick test.

Performance against IVD methodes

Sensitivity and specificity of the ALFA was determined against different *in-vitro* diagnostic test methods (ImmunoCAP® und ALLERG-O-LIQ). Sensitivity was calculated based on a cut-off value of 0.7 IU/mL.

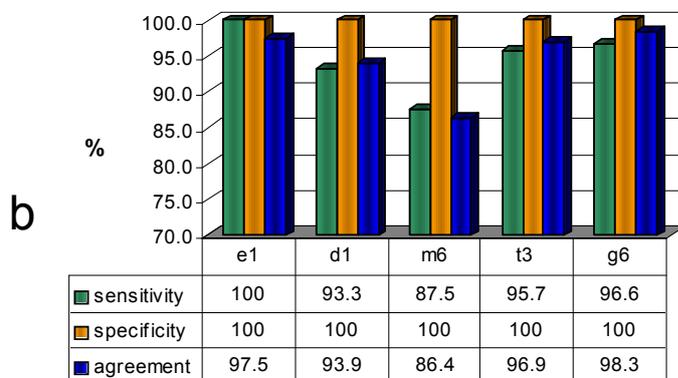
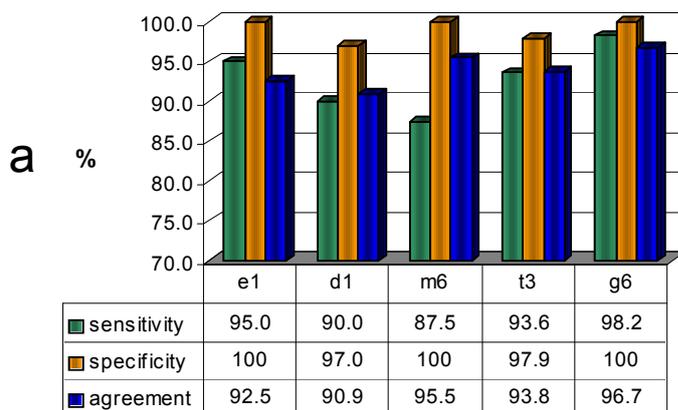


Figure 3
Analytical sensitivity, specificity and agreement of ALFA against ImmunoCAP® (a) and ALLERG-O-LIQ (b) System.

Literature

1. Hamilton RG, Franklin Adkinson N Jr: **In-vitro assays for the diagnosis of IgE-mediated disorders.** *J Allergy Clin Immunol* 2004; **114**: 213-25.
2. Lucassen R, Fooke M, Kleine-Tebbe J, Mahler M: **Development and Evaluation of a Rapid Assay for the Diagnosis of IgE-mediated Type I Allergies.** *J Investig Allergol Clin Immunol.* 2008; **18** (3):223-30.
3. Lucassen R, Fooke M, Lorenz C, Kleine-Tebbe J, Mahler M: **Evaluation of a rapid assay for the diagnosis of type I allergy.** Abstract: EAACI 2008 Barcelona, Spain.