ALFA (Allergy Lateral Flow Assay)

Rapid test for the qualitative determination of allergen specific IgE (sIgE) in whole blood, serum or plasma

The worldwide frequency of allergies has increased significantly over the past decades. The term allergy is 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.

ALFA (Allergy Lateral Flow Assay) is a rapid test for the qualitative determination of allergen specific Immunoglobulin E (sIgE).

sIgE ALFA Specifications

- Serum, plasma and whole blood applicable
- Large palette of single allergens and allergen mixtures available (see current list of ALFA allergens)
- Recombinant and native, highly purified allergen components are available (see current list of recombinant and native allergens)
- Test results in 20 min
- Quantitative evaluation and documentation with the help of the LFA (Lateral Flow Assay) Reader in Units (U/mL) and Classes, analog to RAST Classes, possible
- Excellent correlation with skin prick test and other in-vitro test methods for sIgE (Figure 2 und 3)

ALFA single-strip cassette	REF 1800010	Σ 20
ALFA eight-strip cassette	REF 184000	Σ 80

ALFA Test procedure

ALFA consists of a uniform test device - the ALFA Basis Set - in combination with several arbitrary single- or allergen-mixture-solutions (screens).

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).

Two different test formats are available, a single-strip and an eight-strip cassette.

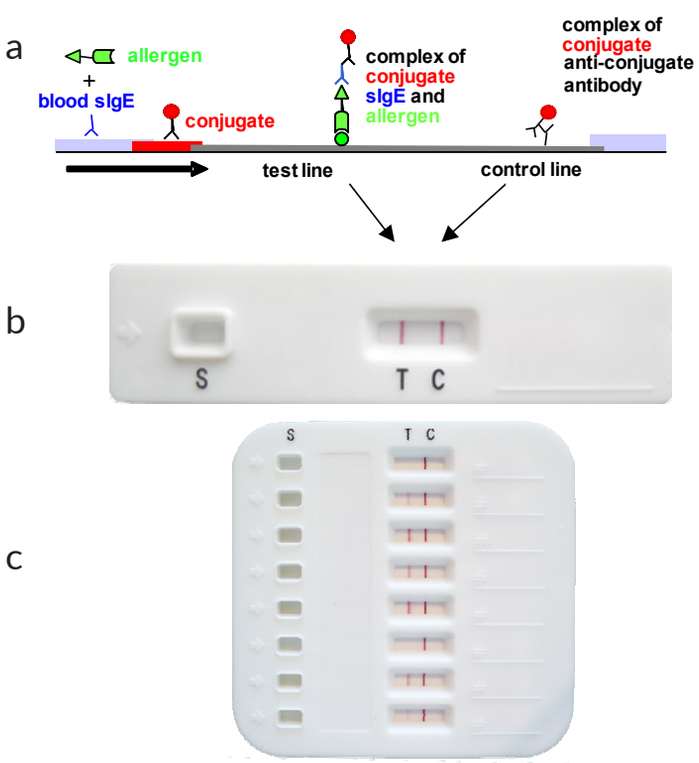

Figure 1
a) Test principle ALFA, b) Positive result (single-strip cassette), c) Different results (eight-strip cassette).

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Performance against skin prick test and nasal Provocation

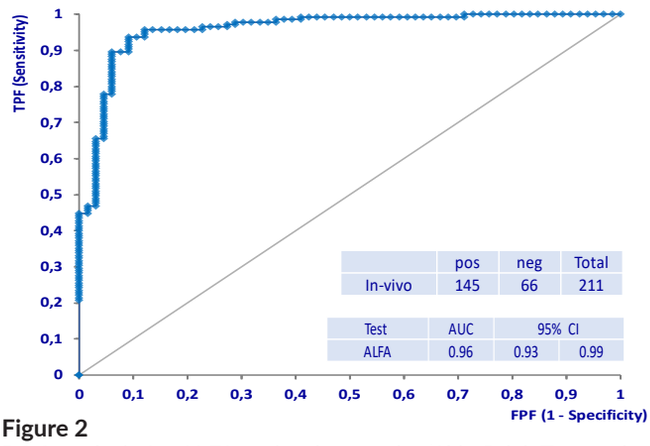

Figure 2
ROC analysis for ALFA vs. in-vivo results (Skin Prick Test and nasal Provocation) for five different allergens (d1, d2, g6, t3 and t4) with n=211 results.

Area under the curve (AUC) value of ALFA compared to 211 in-vivo results were found > 0.95. Compared to in-vivo results ALFA shows a sensitivity of 0.96 (Confidence interval, CI 0.92-0.98) and specificity of 0.85 (CI 0.74-0.92).

Performance against IVD methodes

Sensitivity and specificity of ALFA was determined against different in-vitro diagnostic test methods (ImmunoCAP® und ALLERG-O-LIQ).

	Number of negative / positive results with ImmunoCAP®		ALFA vs ImmunoCAP®		
Allergen	neg	pos	AUC	Sensitivity (%)	Specificity (%)
d1 (*Der. pteronyssinus*)	25	47	0.95	91.5	92.0
d2 (*Der. farinae*)	26	49	0.97	91.3	96.2
g6 (Timothy Grass)	14	58	0.97	96.6	92.9
t3 (Birch)	19	53	0.97	96.2	89.5
t4 (Hazel)	21	51	0.97	92.2	90.5

Table 1
Agreement between ImmunoCAP® and ALFA results for d1, d2, g6, t3 and t4 (n=72 patient samples).

Excellent agreements were observed between ALFA results and ImmunoCAP® results. AUC values were found at > 0.95 for each allergen (see table 1) and 0.97 for all allergens (see figure 3A) compared to ImmunoCAP® results.

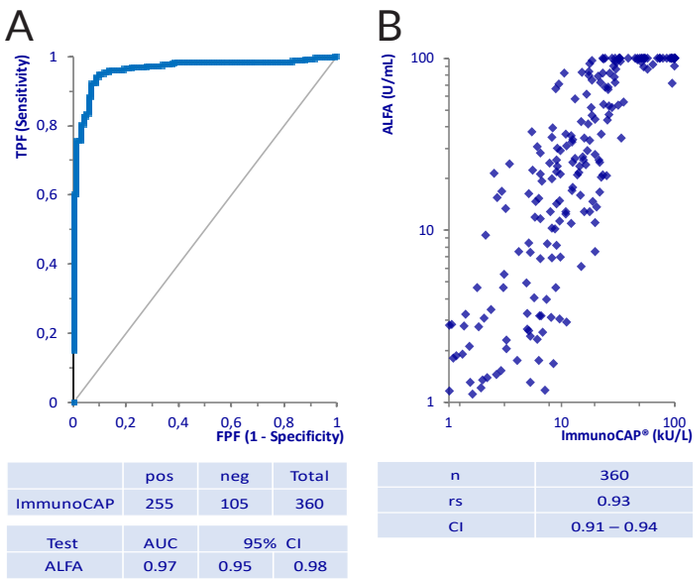

Figure 3
A) ROC analysis for ALFA vs. ImmunoCAP® for five different allergens (d1, d2, g6, t3 and t4) with n=360 results. B) Spearman correlation between ALFA and ImmunoCAP® for five different allergens (d1, d2, g6, t3 and t4) with n=360 results.

Agreements between ALFA and ImmunoCAP® according to Spearman were found at 0.92 for d1 (CI 0.87-0.95), 0.92 for d2 (CI 0.97-0.95), 0.96 for g6 (CI 0.94-0.98), 0.95 for t3 (CI 0.92-0.97) and 0.91 for t4 (CI 0.86-0.94). Spearman correlation between ALFA und ImmunoCAP® for all five allergens reveals a coefficient of 0.93 (CI 0.91-0.94, see figure 3B). AUC value of ALFA compared to 497 ALLERG-O-LIQ results were found at 0.95 with a sensitivity of 0.92 (CI 0.87-0.95) and specificity of 0.84 (CI 0.74-0.92) (see figure 4).

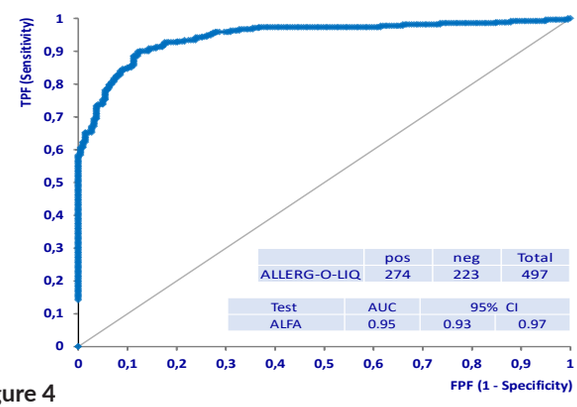

Figure 4
ROC analysis for ALFA vs. ALLERG-O-LIQ results for five different allergens (d1, d2, g6, t3 and t4) with n=497 results.

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. Reicke B, Offermann N, Fooke M: **Evaluation of a scanner based allergy lateral flow assay system for the determination of specific IgE within 20 minutes.** Oral Poster Presentation: EAACI 2017, Helsinki, Finland.

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