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NEWSLETTER



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Clinical evaluation of a new allergy lateral flow assay for professional and home use

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Background: A new allergy screening test (Allergy Lateral Flow Assay; ALFA™) for the qualitative detection of sIgE (specific IgE) in human serum, plasma or whole blood was evaluated for professional and home use.

Methods: Untrained volunteers (n=96) performed ALFA™ Seasonal Screen (S) and ALFA™ Perennial Screen (P) with 25 µL capillary blood. Additionally, a professional user performed the test using testpersons' blood sample. The sIgE to all allergens contained in both ALFA™ S and P was measured by ALLERG-O-LIQ. Furthermore, skin prick tests (SPT, Allergopharma, Germany) were performed. ALFA™ results and patients clinical diagnosis were analysed using different statistical methods. If ALFA™ results and the testpersons' diagnosis were not concordant, ALFA™ was repeated with 30 µL of testperson serum.

ALFA™ Perennial Screen (P)

Code	Allergen
d1	<i>D. pteronyssinus</i>
d2	<i>D. farinae</i>
e1	cat
e2	dog
m3	<i>Aspergillus fumigatus</i>
m33	<i>Aspergillus niger</i>

ALFA™ Seasonal Screen (S)

Code	Allergen
t3	Birch
g2	Bermuda Grass
g5	Perennial Rye Grass
g6	Timothy Grass
g8	June Grass
g12	Cultivated Rye
w6	Mugwort
m6	<i>Alternaria alternata</i>



Figure 1 ALFA™ allergen composition (left) and kit components (right)

a.)			b.)		
	Patient S	Control S		Patient P	Control P
ALFA S +	25	2	ALFA P +	6	1
ALFA S -	8	56	ALFA P -	10	66

c.)			d.)		
	Patient	Control		Laymen +	Laymen -
ALFA +	31	3	Prof. +	31	3
ALFA -	18	122	Prof. -	3	137

Figure 3 Correlation of ALFA™ a.) Seasonal-, b.) Perennial Screen and c.) combined to doctor's diagnosis and d.) between laymen vs. professional user (kappa = 0.89; $p < 0.0001$) for ALFA™ Perennial- and Seasonal Screen combined

Table 1 Assay performance of ALFA™

	ALFA™ S	ALFA™ P	ALFA™ S + P
Sensitivity	75.8	37.5	63.3
Specificity	96.6	98.5	97.5
DE	89.0	88.2	87.9
PPV	92.6	85.7	91.2
NPV	87.5	97.1	87.1
kappa	0.75	0.46	0.67
p	< 0.0001	< 0.0001	< 0.0001
chi square	49.3	17.3	79.1

DE = diagnostic efficiency; PPV = positive predictive value; NPV = negative predictive value

a.)			b.)		
	serum +	serum -		serum +	serum -
blood +	0	0	blood +	0	0
blood -	10	3	blood -	8	2

c.)		
	serum +	serum -
blood +	0	0
blood -	18	5

Figure 5 Correlation of ALFA™ results received with whole blood vs. the respective serum of ALFA™ negative test persons with type one allergy [a.) ALFA™ Perennial Screen, b.) Seasonal Screen and c.) combined]

Conclusion:

- ALFA™ is a fast and robust first line screening test for the qualitative detection of sIgE for professional and home use.
- Results for seasonal allergens are in very good agreement with doctor's diagnosis.
- ALFA™ Perennial Screen shows good sensitivity when used as professional test with serum as specimen, thus sensitivity limitation is restricted to use with whole blood. The home use test is currently under optimization and will become available with increased sensitivity.
- ALFA™ offers the opportunity for primary care physicians and patients to perform a screening test for type-I allergy for early diagnosis of allergic conditions.

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ALFA Reader *opTrilyzer*[®] *Plus*

The LFA (Lateral Flow Assay) Reader is a mobile measuring device for the quantitative evaluation and documentation of **ALFA** (Allergy Lateral Flow Assay) and rapid tests for the determination of sIgE (ALFA).



Figure 1 LFA Reader

- Quantitative Evaluation
 - Measuring results in Units (U/mL) (ALFA and AI-LFA)
 - Allocation in classes (analog to RAST classes) (ALFA)
- Dokumentation of the results by
 - Printout (provided printer)
 - Storage on the internal memory of the device
 - Export of results
- Simplified use by an intergrated Barcode Scanner for importing allergens and patient samples
- Single- and eight-strip cassettes can be read



Figure 2 Report printout LFA Reader for ALFA



Figure 3 a) different results (eight-strip cassette); b) positive result (single-strip cassette)



CODE	DESIGNATION	CDT
	IgE Total Eet accessoires	
183000	ALPFA IgE TOTAL LATERAL FLOW	20
08102CP	IgE TOTAL ELISA HRP	96
1800010	ALFA Cassette vierge monotest	20
184000	ALFA Cassette vierge 8 tests	10
	IgE Spécifiques	
18-F 002	ALFA Allergen solution lait de vache	20 det
18-F 078	ALFA Allergen solution caséine	20 det
18-F 076	ALFA Allergen solution alpha-lactalbumin	20 det
18-F 077	ALFA Allergen solution beta-lactoglobulin	20 det
18-F 001	ALFA Allergen solution blanc d'œuf	20 det
18-F 075	ALFA Allergen solution jaune d'œuf	20 det
18-F 013	ALFA Allergen solution Cacahuète	20 det
18-FX150	ALFA Allergen solution FISH Screen	20 det
18-FX152	ALFA Allergen solution Noisettes Screen (f16, f17, f20)	20 det
18-F010	ALFA Allergen solution Sésame	20 det
18-f014	ALFA Allergen solution Soja	20 det
18--f092	ALFA Allergen solution Resin	20 det
18-F093	ALFA Allergen solution Fromage Roquefort	20 det
18-F033	ALFA Allergen solution orange	20 det
18-Fx151	ALFA Allergen solution fruits screen (f49, f53)	20 det
18-F044	ALFA Allergen solution fraise	20 det
18-F035	ALFA Allergen solution pomme de terre	20 det
18-F025	ALFA Allergen solution tomate	20 det
18-F024	ALFA Allergen solution crevette	20 det
18-D001	ALFA Allergen solution Dermatophagoides pteronyssinus	20 det
18-D002	ALFA Allergen solution Dermatophagoides farinae	20 det
18-I006	ALFA Allergen solution blatte	20 det
18-Gx001	ALFA Allergen solution Graisses screen	20 det
18-T009	ALFA Allergen solution olives	20 det
18-Ex001	ALFA Allergen solution Epitheliums 1 animal	20 det
18-T016	ALFA Allergen solution Pin blanc	20 det
18-Gx004	ALFA Allergen solution Mais mélange	20 det
18-T023	ALFA Allergen solution Cyprès	20 det
18-T019	ALFA Allergen solution Banane	20 det
18-W007	ALFA Allergen solution marguerite	20 det
18-W021	ALFA Allergen solution paroi pariétaire	20 det
18-M003	ALFA Allergen solution WII Aspergillus fumigatus	20 det
18-M006	ALFA Allergen solution WII Alternaria alternata	20 det
18-E001	ALFA Allergen solution Chat	20 det
18-E005	ALFA Allergen solution Chien	20 det
18-k082	ALFA Allergen solution latex	20 det

