



# 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
p1	D. pteronyssinus
p2	D. farinae
p3	cat
p4	dog
p5	Aspergillus fumigatus
p6	Aspergillus niger

## ALFA™ Seasonal Screen (S)

Code	Allergen
s1	Birch
s2	Bermuda Grass
s3	Perennial Rye Grass
s4	Timothy Grass
s5	June Grass
s6	Cultivated Rye
s7	Mugwort
s8	Alternaria alternata



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

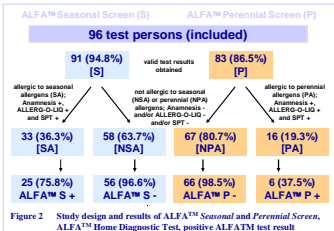
  

c.)		
	serum +	serum -
blood +	0	0
blood -	18	5

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.



**Results:** Agreement between ALFA™ results and doctor's diagnosis was 94.5% for S, 91.6% for P and 93.1% for ALFA™ S + P combined. For performance data see figure 3 and 4.