



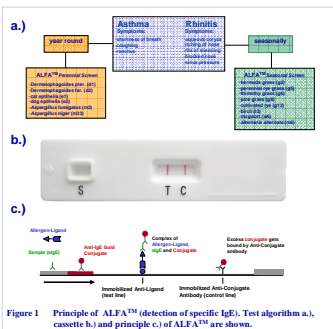
Development and evaluation of a rapid assay for the diagnosis of type I allergies

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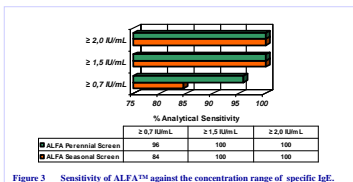
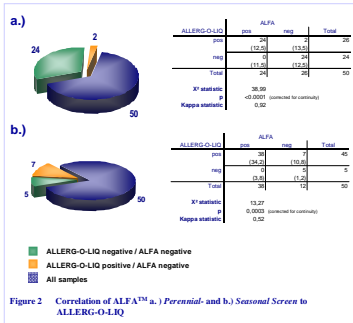
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Background: Specific IgE (sIgE) is a marker for allergy diagnosis. We present a new type of Allergy Screening Test (ALFA™ = Allergy Lateral Flow Assay) for the qualitative detection of sIgE in human whole blood, serum or plasma. ALFA™ is based on a uniform test device which can be combined with several arbitrary allergen solutions determining the specificity of the test. The objective of our study is the evaluation of ALFA™.

Methods: Serum samples (n=50) were tested by ALFA™ *Seasonal Screen* and ALFA™ *Perennial Screen*. Sera were also tested for specific IgE to all single allergens (contained in ALFA™ allergen screens) by ALLERG-O-LIQ and selected samples for sIgE by the ImmunoCAP® system.



Results: Depending on the allergen solution as well as the cohort of sera the average analytical sensitivity of ALFA™ varied between 84% and 100% with an analytical specificity of 100%. Good agreement between ALFA™ and ALLERG-O-LIQ or ImmunoCAP® was observed (see Figure 2, 3).



Conclusion:

- ALFA™ is a reliable, simple to use and rapid first line screening test for type I allergies
- good correlation to established methods for the detection of specific IgE (e.g. ALLERG-O-LIQ, ImmunoCAP®)
- good sensitivity and excellent specificity (100%)
- sera below 0.7 IU/mL are tested positive with a sensitivity of 84 or 96%, depending on allergen screen