Evaluation of a scanner based allergy lateral flow assay system for the determination of Total IgE

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Background: Total IgE (Immunoglobulin E) levels can be elevated in patients suffering from allergies, parasitic infections, allergic bronchopulmonary aspergillosis or atopic dermatitis. ALFA (Allergy Lateral Flow Assay) Total IgE is a rapid test for the qualitative determination of Total IgE in human serum, plasma or whole blood (see figure 1). The use of a special scanner system provides the opportunity of semi-quantitative interpretation of ALFA results within 25 minutes. The objective of the study is the evaluation of a rapid test for the semi-quantitative interpretation of Total IgE (tIgE) compared with other in-vitro methods.

Methods: Serum samples (n=57) were taken from the serum bank at Dr. Fooke Laboratorien GmbH and tested for Total IgE values by Total IgE ELISA (Dr. Fooke Laboratorien GmbH) and ALFA Total IgE (Dr. Fooke Laboratorien GmbH). Results of ALFA were assessed and interpreted visually and by a special scanner system. Inter- and intra-assay variations of the ALFA Total IgE test were determined with different serum samples.
71 serum samples from a hospital in Koblenz, Germany, were used for the evaluation of the ALFA Total IgE test together with a special scanner system. The results were compared to two established in-vitro methods for the determination of Total IgE (Total IgE ELISA, Dr. Fooke Laboratorien GmbH and ImmunoCAP® Total IgE, ThermoScientific).

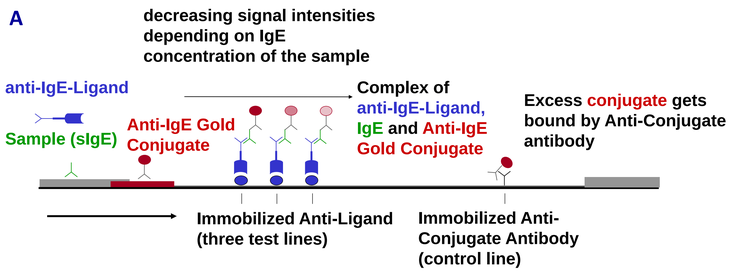

Figure 1 **A) Test principle ALFA Total IgE**
B) Single-strip cassette (positive result)
C) Lateral flow assay reader

Results and findings: Agreement between Total IgE ELISA and ALFA interpreted with the scanner system, according to Spearman were found at 0.94 (confidence interval, CI 0.87-0.95) for 57 serum samples (see figure 2). Inter- and intra-assay variations of the rapid test were observed < 10 %. At a cut-off of 10 IU/mL an area under the curve (AUC) value of 1.00 compared to Total IgE ELISA was found (see figure 3).

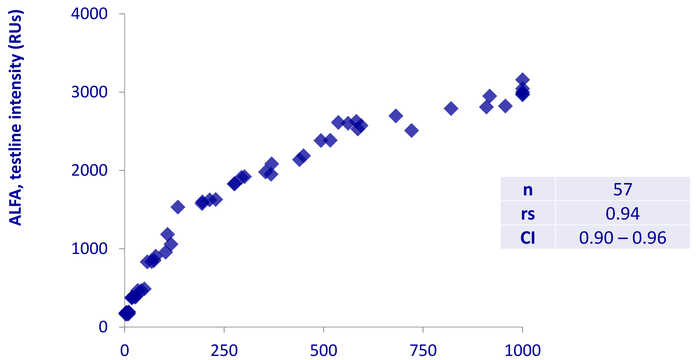

Figure 2 **Spearman correlation between ALFA Total IgE and an ELISA for the determination of total IgE (n=57 patient samples).**

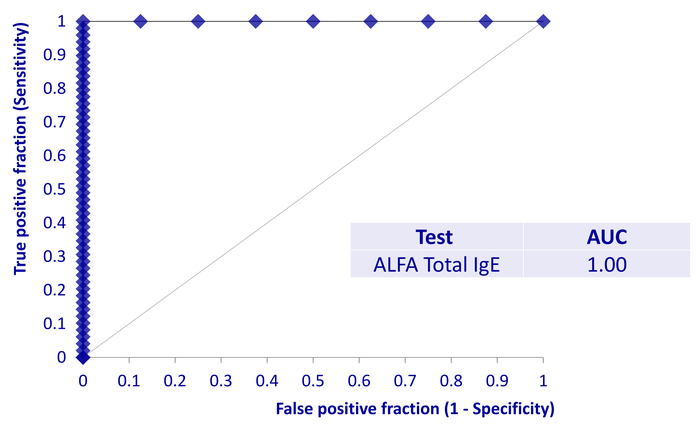

Figure 3 **ROC analysis for ALFA Total vs. an ELISA for the determination od total IgE (n=57 patient samples).**

The testline intensities of ALFA Total IgE were translated in U/mL according to the international WHO standard (11/234) for total IgE.

71 serum samples from allergic patients (provided by a hospital in Koblenz, Germany) show agreement between ALFA and ImmunoCAP® / Total IgE ELISA according to Spearman of 0.98 for the determination of Total IgE. Spearman correlation between ImmunoCAP® and the Total IgE ELISA reveals a coefficient of 0.97 (see figure 4A, 4B, 4C).

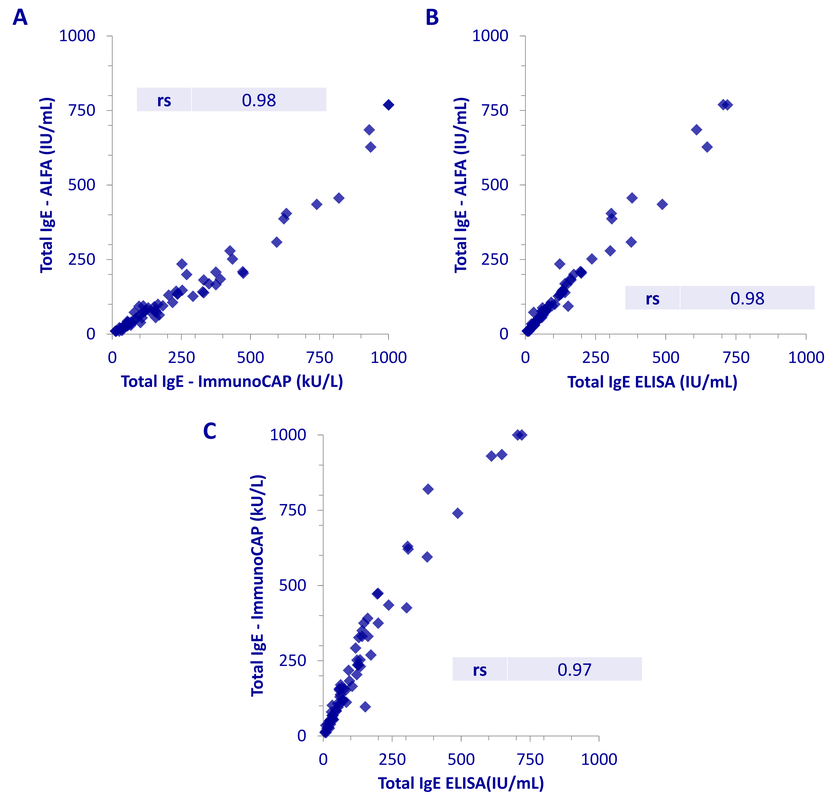

Figure 4 **Spearman correlation between ALFA Total IgE and ImmunoCAP (A) / ELISA for the determination of total IgE from Dr. Fooke Laboratorien (B) and correlation of both ELISA systems (C).**

Conclusion: For the detection of total IgE, ALFA shows a good correlation when compared to ImmunoCAP (ThermoScientific) and Total IgE ELISA (Dr. Fooke Laboratories). AUC of 1.00 indicates an identical performance between the Total IgE ELISA and ALFA. The high precision of the ALFA is supported by the Lateral Flow Assay Reader, especially for weak positive results.

In relation to this presentation, we declare that there are no conflicts of interest

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