

Comparison of a scanner based allergy lateral flow assay system for the determination of specific IgE with other in-vitro and in-vivo methods

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Background: One important parameter for the diagnosis of type I hypersensitivity is the determination of specific immunoglobulins (sIgE) and thus sIgE represents a marker for modern allergy diagnosis. Allergy Lateral Flow Assay (ALFA) is a rapid test for the qualitative determination of sIgE in human serum, plasma or whole blood. The use of a special scanner system provides the opportunity of semi-quantitative interpretation of ALFA results within 20 minutes (see figure 1). The objective of the study is the evaluation of a rapid test for the semi-quantitative interpretation of sIgE compared with other *in-vitro* and *in-vivo* methods.

Methods: Agreement between ALFA (Dr. Fooke Laboratorien GmbH) and ALLERG-O-LIQ (Dr. Fooke Laboratorien GmbH) / ImmunoCAP[®] (ThermoScientific) was investigated using 71 sera tested for specific IgE to *Dermatophagoides pteronyssinus* (d1), *Dermatophagoides farinae* (d2), timothy grass pollen (g6), birch pollen (t3) and hazel pollen (t4). Receiver Operating Characteristic (ROC) analysis and spearman correlations were performed for every single allergen separately and for all five allergens together. Skin Prick test results and/or nasal provocation results (Roxall) of more than 40 patients were compared to three *in-vitro* methods.

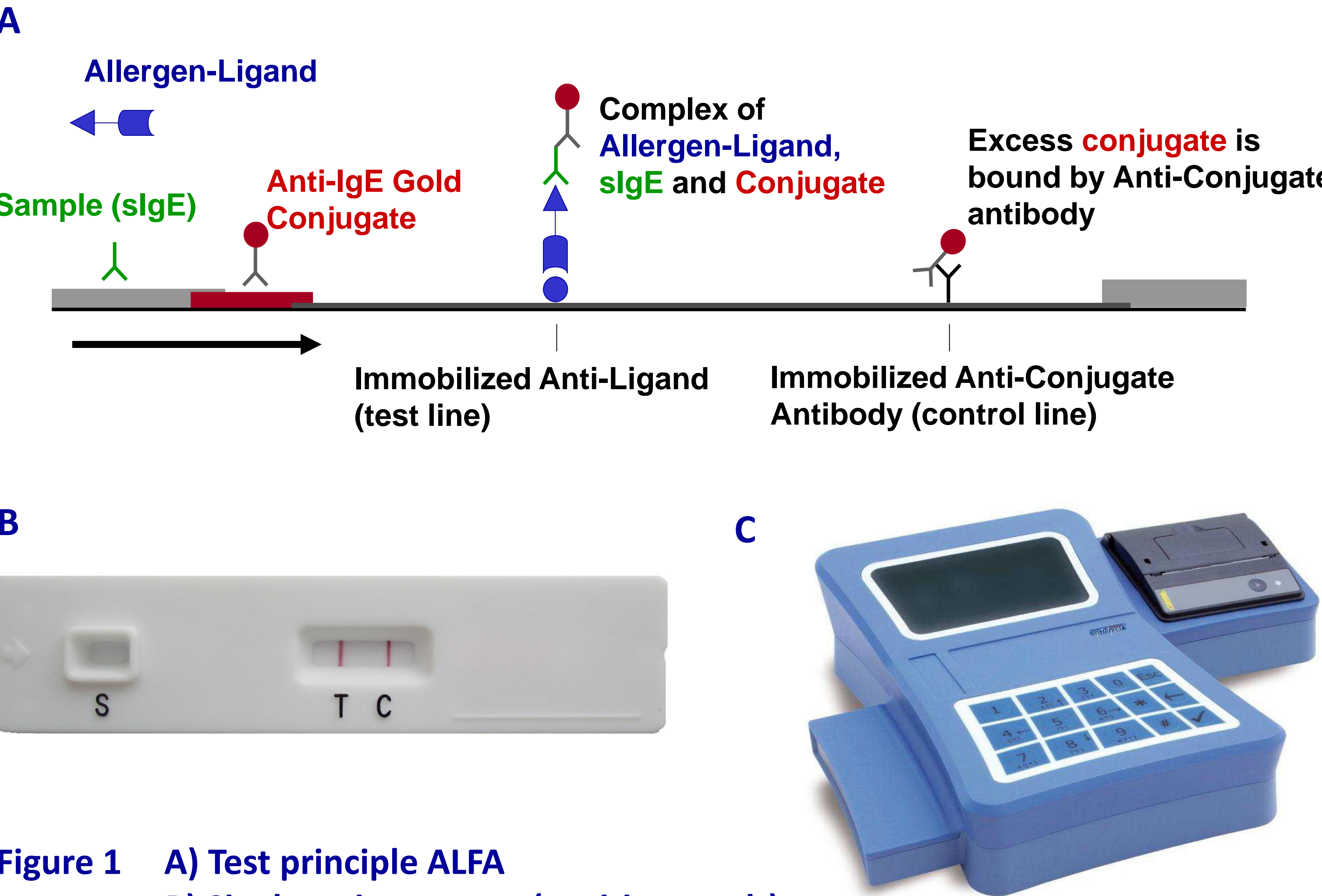


Figure 1 A) Test principle ALFA
B) Single-strip cassette (positive result)
C) Lateral flow assay reader

Results and findings: Excellent agreements were observed between ALFA results and ALLERG-O-LIQ / ImmunoCAP[®] results. Area under the curve (AUC) values were found at > 0.96 for every allergen (see table 1) and 0.97 for all allergens (see figure 2A) compared to ALLERG-O-LIQ and ImmunoCAP[®] results.

Agreements between ALFA and ALLERG-O-LIQ / ImmunoCAP[®] according to Spearman were found at 0.92 / 0.93 for all five allergens (see figure 2B).

Table 1 Agreement between ALFA and ALLERG-O-LIQ / ImmunoCAP[®] results for d1, d2, g6, t3 and t4 (n=71 patient samples).

Allergen	Number of negative / positive results with ImmunoCAP [®]		ALFA vs. ALLERG-O-LIQ / ImmunoCAP [®]		
	neg	pos	AUC	Sensitivity	Specificity
d1 (<i>Der. pteronyssinus</i>)	24	47	0.98 / 0.98	0.85 / 0.96	0.96 / 0.88
d2 (<i>Der. farinae</i>)	25	46	0.96 / 0.98	0.82 / 0.96	0.96 / 0.89
g6 (Timothy Grass)	13	58	0.99 / 0.97	0.97 / 0.97	0.85 / 0.85
t3 (Birch)	19	52	0.96 / 0.96	0.93 / 0.94	0.83 / 0.89
t4 (Hazel)	21	50	0.98 / 0.97	0.86 / 0.96	1.00 / 0.86

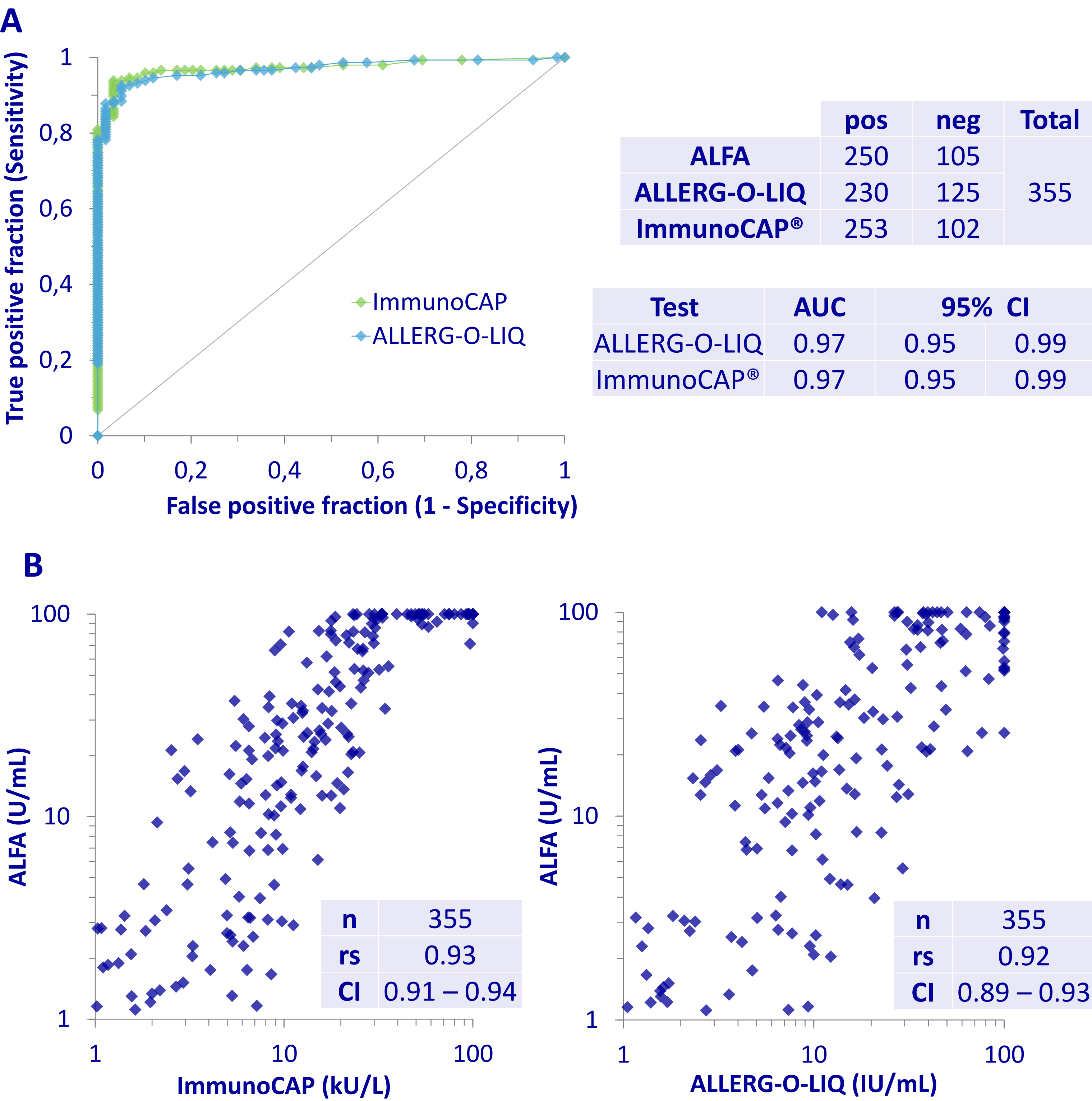


Figure 2 A) ROC analysis for ALFA vs. ALLERG-O-LIQ / ImmunoCAP[®] for five different allergens (d1, d2, g6, t3 and t4) with n=355 results.
B) Spearman correlation between ALFA and ALLERG-O-LIQ / ImmunoCAP[®] for five different allergens (d1, d2, g6, t3 and t4) with n=355 results.

AUC values of all *in-vitro* systems compared to 206 *in-vivo* results were found > 0.96. Compared to *in-vivo* results ALFA showed a sensitivity of 0.84 and specificity of 0.96. Sensitivity and specificity between *in-vivo* results and ALLERG-O-LIQ / ImmunoCAP[®] were found at 0.93 / 0.83 and 0.91 / 0.96, respectively.

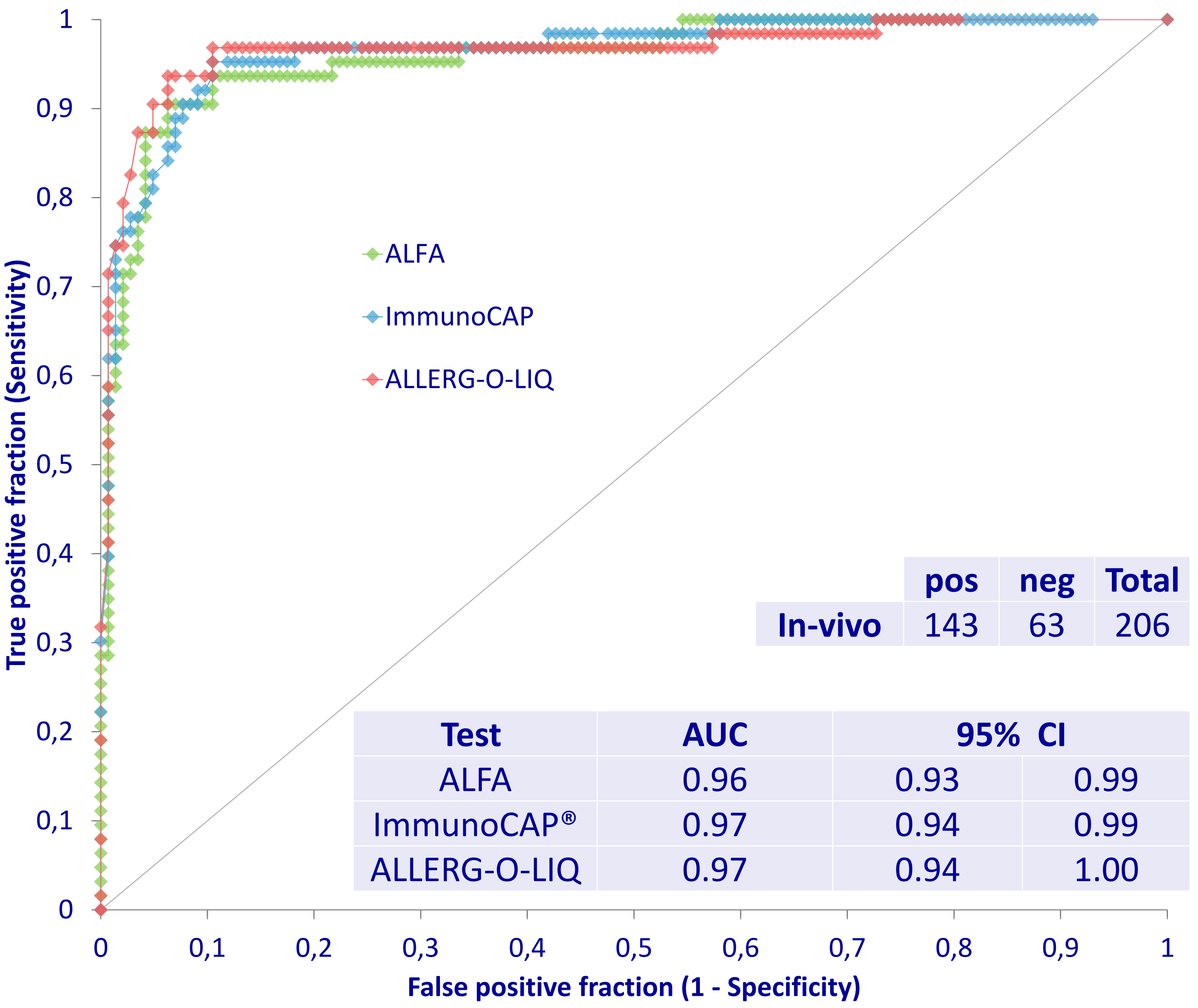


Figure 3 ROC analysis for ALFA (green), ALLERG-O-LIQ (red) and ImmunoCAP[®] (blue) vs. *in-vivo* results for five different allergens (d1, d2, g6, t3 and t4) with n=206 results.

Conclusion: For the detection of sIgE, ALFA shows results of high sensitivity and specificity when compared to ALLERG-O-LIQ, ImmunoCAP[®] and *in-vivo* results. AUCs of > 0.97 indicate a nearly identical performance between ALLERG-O-LIQ / ImmunoCAP[®] and ALFA. The correlation for ALFA versus ALLERG-O-LIQ and ImmunoCAP[®] is also comparable with spearman's rho ≥ 0.92. The high sensitivity of the ALFA is supported by the Lateral Flow Assay Reader, especially for weak positive results.

References:
1. Pfender N, Lucassen R, Offermann N, Schulte-Pelkum J, Fooke M, Jakob T. 2012. Evaluation of a Novel Rapid Test System for the Detection of Specific IgE to Hymenoptera Venoms. J Allergy (Cairo) 2012: 862023

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