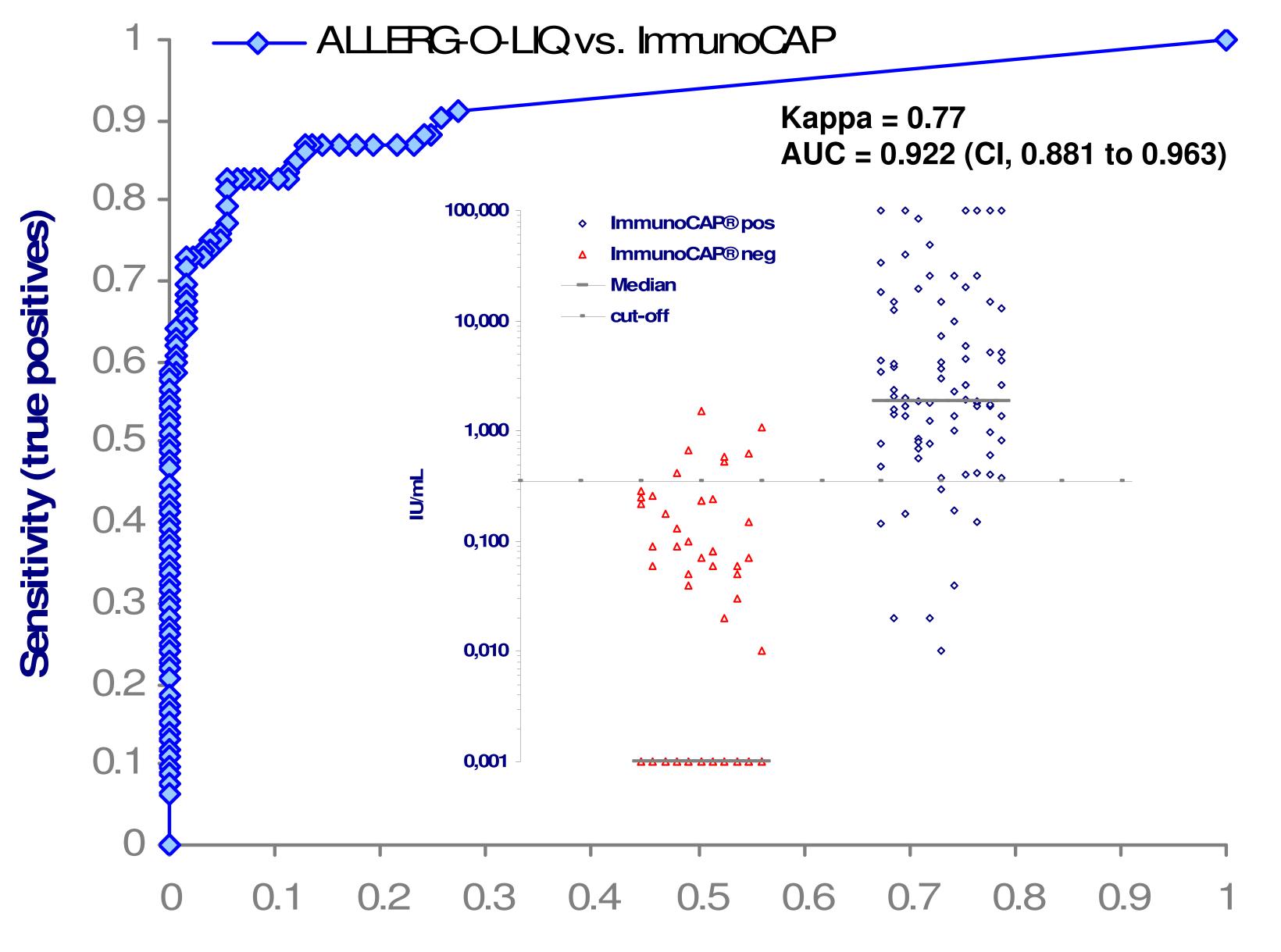
## Allergen-specific IgE-values to inhalant and food allergens in China – Comparison between two commercial immunoassays: Dr. Fooke ALLERG-O-LIQ versus Phadia ImmunoCAP<sup>®</sup> System

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Background: Allergen specific immunoglobulin E represents a hallmark in the diagnosis of (slgE) Although several methods are allergy. type the quantitative determination of available for specific IqE in human serum or plasma the ImmunoCAP® (Phadia, Upsalla, Sweden) is considered as the golden standard. A modern technology, the ALLERG-O-LIQ System (Dr. Fooke Laboratorien, Neuss, Germany) is based on the reversed enzyme allergo sorbent test protocol anti-IgE coated microtiterplates using in combination with biotinylated allergens and streptavidine-HRP conjugate. The objective of our study is the technical comparison of the <u>ALLERG-</u> O-LIQ and ImmunoCAP<sup>®</sup> results.



Methods: Sera from patients (bronchus asthma, allergic rhinitis and chronic cough) were collected from October 2004 to May 2007 at Guangzhou Institute of Respiratory disease out patient department and tested for specific IgE to selected common inhalant [D. pteronyssinus (d1), D. farinae (d2), *blomia tropicalis* (d5), german cockroach (i6), cat epithelia (e1), dog epithelia (e2), Aspergillus *fumigatus* (m3)] and food allergens [egg white (f1), cow's milk (f2), crab (f23), shrimp (f24)] by ALLERG-O-LIQ and ImmunoCAP<sup>®</sup>. Further, samples were assay for total IgE using both methods. Agreement between the results of ALLERG-O-LIQ and ImmunoCAP<sup>®</sup> was statistically evaluated using different methods including kappa agreement, Pearson correlation, positive (PPV) negative predictive value (NPV) and and diagnostic efficiency (DE).

## 1 - Specificity (false positives)

- Figure 2Receiver operating characteristics (ROC) analysis and comparative<br/>descriptive analysis of the specififc IgE results. Kappa agreement and area<br/>under the curve (AUC) were found at 0.77 and 0.922, respectively. Values<br/>below 0.001 IU/mL are shown as 0.001 IU/mL amd values above 100 IU/mL<br/>as 100 IU/mL.
- Table 1
   Assay performance data of the ALLERG-O-LIQ System for specific IgE compared to ImmunoCAP®

	d1	d2	d5	e1	e5	i6	m3	f1	f2	f23	f24
n (all)	20	20	20	20	20	20	20	20	20	20	20
n (positive ALLERG-O-LIQ)	10	10	9	9	11	7	7	10	9	0	0
n (positive ImmunoCAP®)	11	10	11	10	9	9	8	8	8	3	5
2-tailed p	0.0001	<0.0001	0.0007	0.0001	0.0183	0.0009	0.0002	0.0198	0.0001	-	-
Kappa statistic	0.90	1.00	0.80	0.90	0.60	0.79	0.89	0.60	0.90	-	-
X <sup>2</sup> statistic	12.93	16.20	10.29	12.93	5.31	9.97	12.54	5.21	12.80	-	-
р	0.0003	<0.0001	0.0013	0.0003	0.0212	0.0016	0.0004	0.0225	0.0003	-	-
Sensitivity	90.9%	100.0%	81.8%	90.0%	88.9%	77.8%	87.5%	87.5%	100.0%	0.0%	0.0%
Specificity	100.0%	100.0%	100.0%	100.0%	72.7%	100.0%	100.0%	75.0%	91.7%	100.0%	100.0%
Positive predictive value	100.0%	100.0%	100.0%	100.0%	72.7%	100.0%	100.0%	70.0%	88.9%	-	-
Negative predictive value	90.0%	100.0%	81.8%	90.9%	88.9%	84.6%	92.3%	90.0%	100.0%	85.0%	75.0%
Efficiency	95.0%	100.0%	90.0%	95.0%	80.0%	90.0%	95.0%	80.0%	95.0%	85.0%	75.0%

**Results:** Prevalence of positive test results varied between 0/18 (f23/f24) and 11/20 (e5) for ALLERG-O-LIQ and between 3/18 (f23) and 11/20 (e5) for

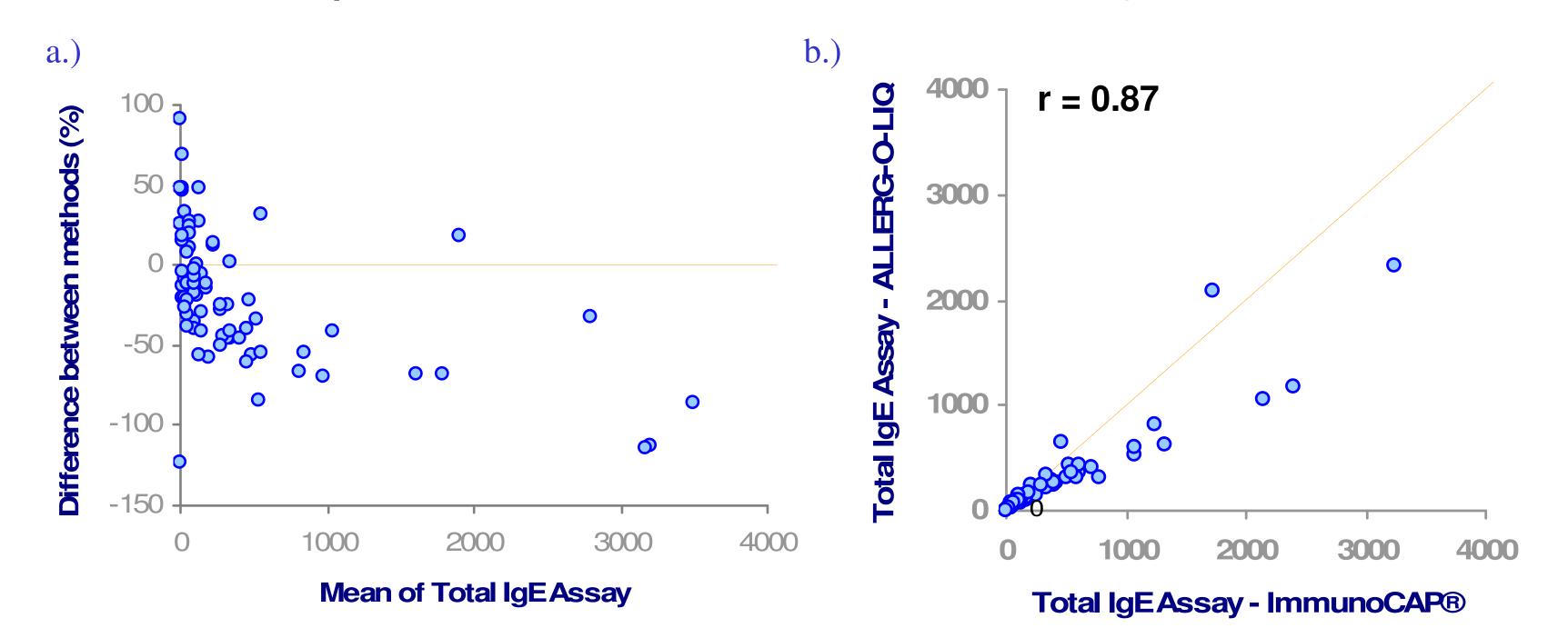


Figure 2Comparison of Total IgE ALLERG-O-LIQ with ImmunoCAP® total IgE.Differences are displayed using bias plot (a.) and agreement is shown in the<br/>Pearson's correlation diagram (b.)

ImmunoCAP<sup>®</sup>. The agreement between both methods was found between 75% (f24) and 100% (d2) depending on the allergen. Overall agreement for inhalant (n=140), food (n=78) and all allergens (n=218) tested was 92.1% (kappa = 0.84; p < 0.0001), 83.3% (kappa = 0.59; p < 0.0001), 89.1%= 0.77; p < 0.0001), respectively. (kappa Sensitivity, specificity, PPV, NPV and DE were found at 88.2%, 95.8%, 95.2%, 89.6%, 92.1% (inhalant allergens), 62.5%, 92.9%, 78.9%, 85.2%, 81.5% (food allergens) and 81.5%, 94.5%, 91.5%, 87.7%, 89.1% (all allergens). Agreement between the total IgE results (n=79) was found at r = 0.87(according to Pearson).

## **Conclusion:**

Good to excellent agreement between ALLERG-O-LIQ and ImmunoCAP® was found
The degree of agreement depended on the allergen and was higher in the group of inhalant allergens
The ALLERG-O-LIQ System represents a reliable test for the quantitative detection of specific and total IgE