Development and evaluation of a new rapid assay for semi-quantitative detection of total IgE in human serum and capillary blood

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Background: Total IgE (Immunoglobulin E) levels can be elevated in patients suffering from allergies and various other disorders such as parasitic infections, allergic bronchopulmonary aspergillosis or atopic dermatitis. Recently, a rapid assay has been developed which uses three individual test lines for the detection of total IgE. The number and intensity of the colour-reaction of the three test lines is proportional to the amount of immune complexes. The objective of our study is the evaluation of ALFA™ (**A**llergy **L**ateral **F**low **A**ssay) Total IgE.

Methods: Serum samples (n=54) were taken from the serum bank at Dr. Fooke Laboratories and tested for total IgE values by Total IgE ELISA (Dr. Fooke Laboratorien, Neuss, Germany) and ALFA™ Total IgE (Dr. Fooke Laboratorien). Results of ALFA™ were assessed and interpreted visually by three independent and untrained observers (OS) by considering the number (0-3) and colour intensity of the test lines by means of an evaluation card. To assess the reproducibility of the test, 6 samples were tested in triplicate determination by three validation batches (VB).

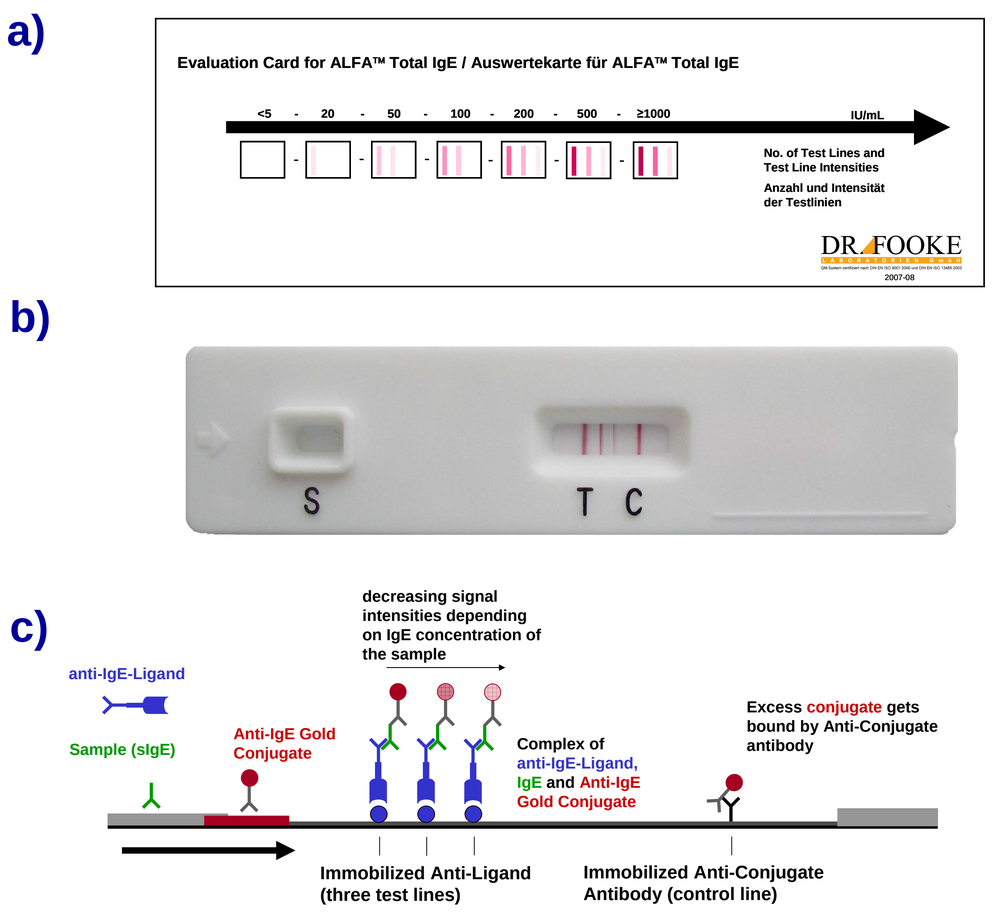

Figure 1 ALFA™ Total IgE evaluation card a), ALFA™ Total IgE cassette b) and principle of ALFA™ Total IgE c) are shown.

Results: The agreement between the results provided by three independent OS as expressed by Pearson's correlation was found at 0.75 (OS1 vs. OS2), 0.86 (OS2 vs. OS3) and 0.82 (OS1 vs. OS3). The agreement between the mean values of all three independent observers and the results of the Total IgE ELISA was 0.96 (see Figure 2-3). Reproducibility test showed consistent results (see Table 1).

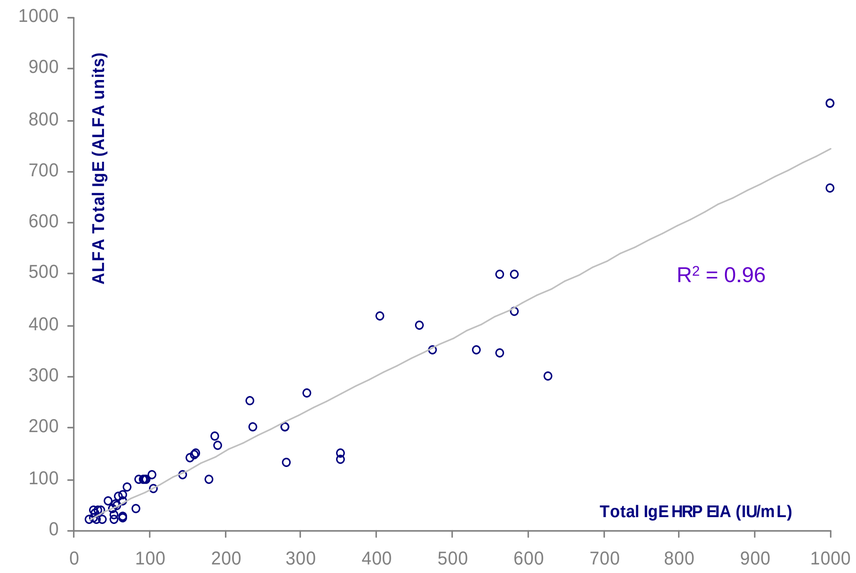

Figure 2 Pearson`s correlation (mean of 3 observers) of ALFA™ Total IgE to Total IgE ELISA

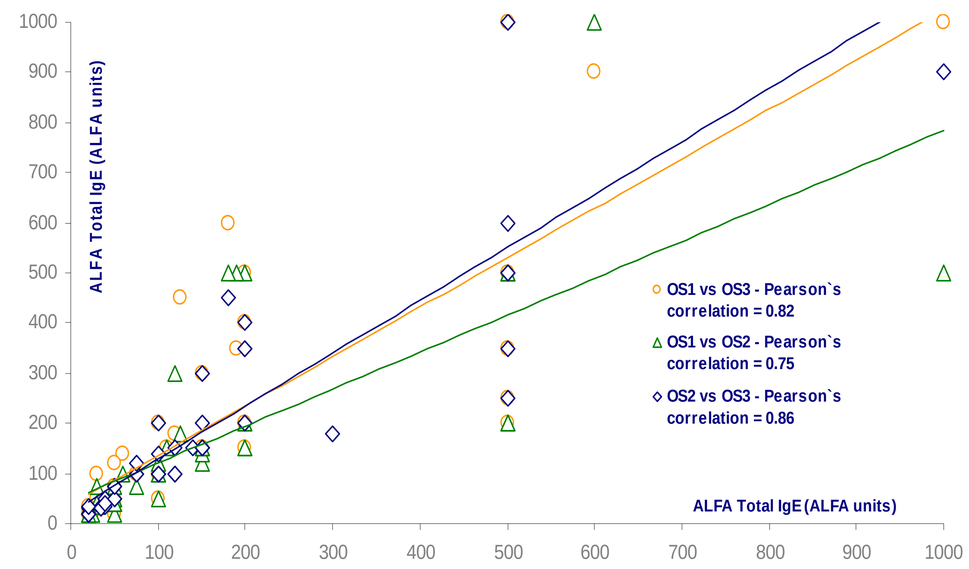

Figure 3 Pearson`s correlation of ALFA™ Total IgE results between OS 1, OS 2 and OS 3

		ALFA Total IgE VB1				ALFA Total IgE VB2				ALFA Total IgE VB3				
sample ID	IU/mL Total IgE	Assay 1	Assay 2	Assay 3	CV%	Assay 1	Assay 2	Assay 3	CV%	Assay 1	Assay 2	Assay 3	CV%	Mean CV%
1	21	20	20	20	0	20	20	20	0	20	20	20	0	0
2	54	35	35	50	18	50	50	50	0	35	50	50	16	11
3	104	100	100	100	0	100	100	100	0	100	150	100	20	7
4	145	100	150	150	18	150	150	150	0	150	150	100	18	12
5	188	150	200	200	13	200	200	200	0	200	150	200	13	9
6	1000	1000	1000	1000	0	1000	500	1000	28	1000	500	1000	28	19

Table 1 Reproducibility of ALFA™ Total IgE results in ALFA units (IU/mL, Inter-Assay/ Inter-Batch Variation)

Conclusion:

- ALFA™ Total IgE represents a reliable and easy to use tool for medical practitioners and allergologists to perform on-site testing for total IgE in the early diagnosis of abundant diseases
- Mean Pearson's correlation of ALFA™ Total IgE to CE-marked Total IgE ELISA was found at 0.96
- Variation between trained observers is low (Pearson`s correlation between 0.75 and 0.86)
- ALFA™ Total IgE shows consistent results (CV% ≤ 15)

2008-02

presented at **EAACI Barcelona 2008**

DR. FOOKE LABORATORIEN GmbH

QM-System zertifiziert nach DIN EN ISO 9001:2000 und DIN EN ISO 13485:2003