



Evaluation of a rapid assay for the diagnosis of type I allergy

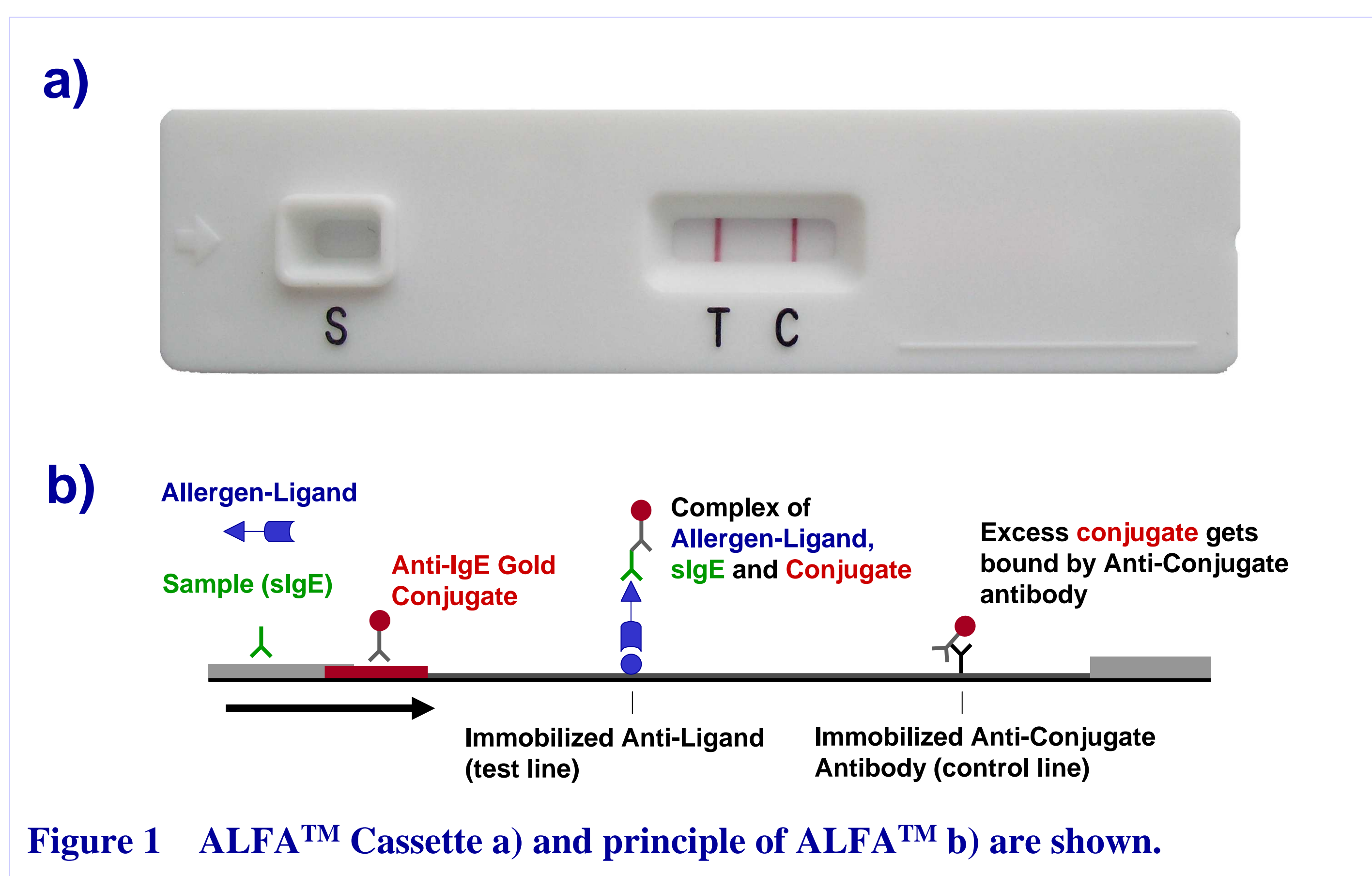
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Background: Specific immunoglobulin E (sIgE) represents a serological marker of state of the art allergy diagnosis. The objective of our study is the evaluation of ALFA™ (Allergy Lateral Flow Assay) detecting sIgE to five important inhalant allergens [cat epithelia (e1), *Der. pteronyssinus* (d1), *Alternaria alternata* (m6), birch (t3) and timothy grass (g6)].

Methods: sIgE of undiagnosed volunteers to e1, d1, m6, t3 and g6 was measured by ALLERG-O-LIQ (Dr. Fooke Laboratorien GmbH, Neuss, Germany) and skin prick tests (SPT) were performed (Allergopharma, Reinbek, Germany). Positive specimens (cut-off 0.35 IU/mL) for e1 (n=20), d1 (n=33) m6 (n=11), t3 (n=48), g6 (n=60) and the same number of negative specimens (< 0.35 IU/mL) for each allergen were assayed by ALFA™ (Dr. Fooke Laboratorien) and ImmunoCAP® (Phadia, Uppsala, Sweden).



Results: At a cut-off value of 0.7 IU/mL, 17/17 (e1), 29/30 (d1), 7/8 (m6), 45/47 (t3) and 57/59 (g6) of sera positive by ALLERG-O-LIQ were also positive by ALFA™. *Kappa* values were found at **0.98** for e1, **0.94** for d1, **0.86** for m6, **0.94** for t3 and **0.98** for g6. Similar results were obtained when ALFA™ was compared to ImmunoCAP® and SPT. 19/20 (e1), 27/30 (d1), 7/8 (m6), 44/47 (t3) and 56/57 (g6) of sera positive by ImmunoCAP® and 19/21 (e1), 27/34 (d1), 8/9 (m6), 44/50 (t3) and 57/66 (g6) of sera positive by SPT were also positive by ALFA™. Sensitivities, specificities and agreements (%) are shown in figure 2.

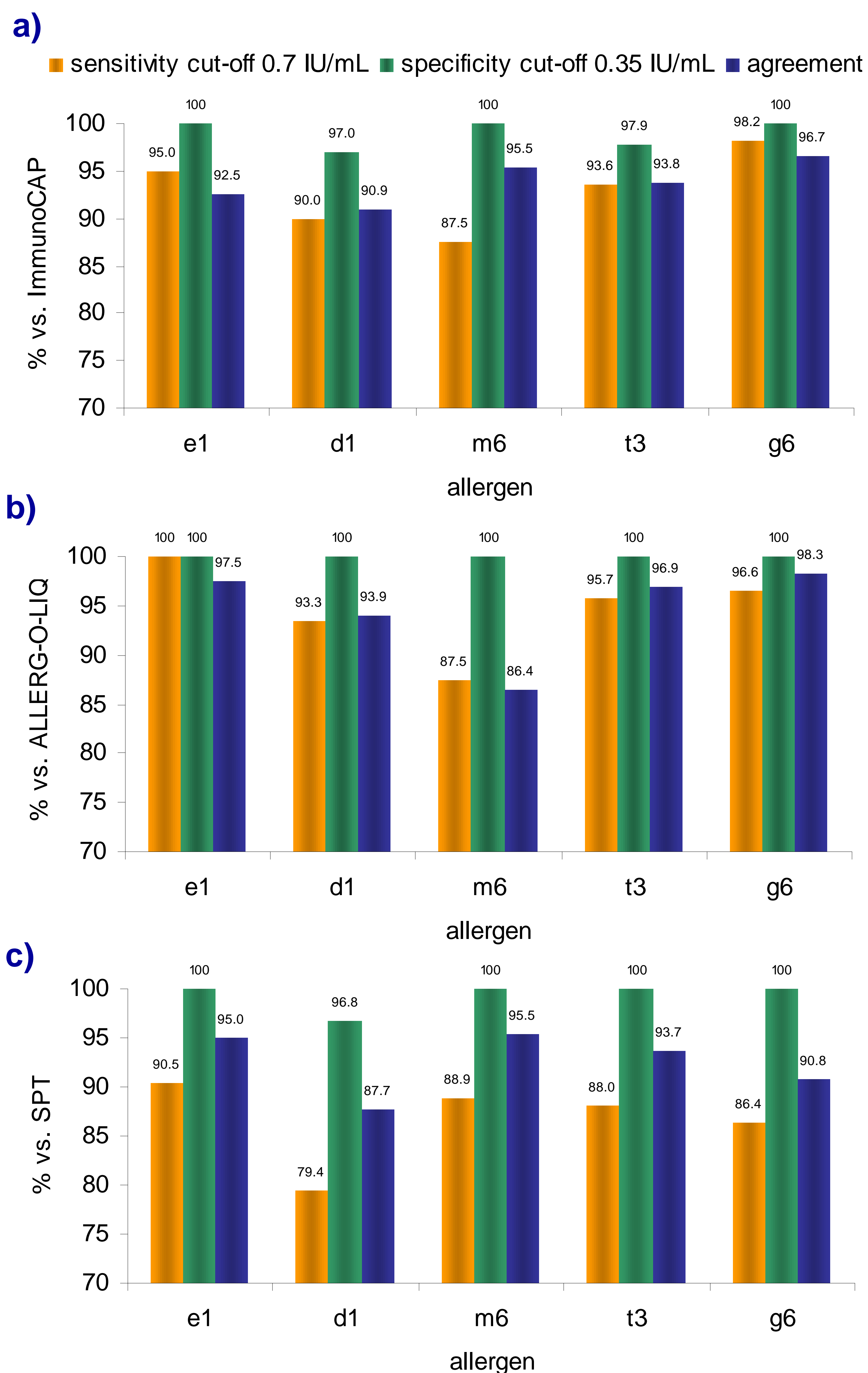


Figure 2 Technical sensitivity, specificity and agreement of ALFA™ vs. different diagnostic assays. a) ALFA™ vs. ImmunoCAP®, b) ALFA™ vs. ALLERG-O-LIQ and c) ALFA™ vs. SPT.

Conclusion:

- ALFA™ represents a reliable and easy to use tool for medical practitioners and allergologists to perform on-site testing for sIgE in the early diagnosis of type I allergies
- very good technical sensitivities and specificities compared to ImmunoCAP®, ALLERG-O-LIQ and SPT