Diagnostic value of positive result for recombinant allergen Api m 1 and Ves v 5 determined by IgE multiplex test ImmunoCAP ISAC: results of multicenter study

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Background: In the allergy field, the IgE multiplex test ImmunoCAP ISAC (ISAC) is an additional diagnostic tool for the assessment of complex cases. When using the ISAC chip in a routine clinical laboratory setting positive result for recombinant allergen Api m 1 and Ves v 5 is frequently observed. In this multi-center study, we evaluated the meaning of this positive result and its clinical relevance.

Methods: This study evaluated results of 2877 ISAC test for rVes v 5 and / or rApi m 1. Positive results for rVes v 5 and rApi m 1 from ISAC were compared with ImmunoCAP (CAP) results. Clinical relevance of the result for honeybee venom or wasp venom allergy was established based on a patient clinical history.

Results: From all analyzed ISAC results 12% had positive IgE antibodies against rVes v 5 and 9% against rApi m 1 allergen. Positive IgE reactivity for rVes v 5 and rApi m 1 determined with ISAC was compared with CAP’s reactivity for the two allergens on 118 and 37 patients, respectively. Among them 85 (55%) patients had clinical data available; in 29% wasp and in 40% honeybee venom allergy was clinically confirmed. Diagnostic sensitivity / specificity of ISAC in comparison to CAP was for rVes v 5 94% / 87% and for rApi m 1 75% / 95%, respectively.

Conclusions: Diagnostic accuracy, for major Hymenoptera venom allergens, of ISAC multiplex IgE assay is comparable to ImmunoCAP singleplex IgE test. Thus all positive results for rVes v 5 and rApi m 1 determined with ISAC have to be interpreted carefully by the clinician with relevant clinical data of the patient.