BACKGROUND: Our aims were to evaluate the performance of a fully automated system for measuring circulating allergen-specific IgE (sIgE) against an established in vitro assay and to assess the system's diagnostic accuracy against objective clinical criteria for identifying sensitization to specific allergens. METHODS: Using both the IMMULITE 2000 Allergy system (IML) and an assay based on the widely used ImmunoCAP technology (CAP), we measured sIgE in serum samples from 169 persons with suspected allergies to airborne or insect venom allergens. Skin testing outcome served as the clinical comparison method. RESULTS: Interassay classification agreement between the IML and CAP, relative to the usual allergen-specific IgE cutoff of 0.35 kIU/L, ranged from 76% (yellow jacket venom) to 95% (orchard grass); agreement was 88.3% for all 9 allergens combined (766 results). The 90 discordant results, when resolved by skin testing, showed better agreement with the IML (72%) than with the CAP (28%). Compared with skin testing, for each of the 9 allergens studied, the area under the ROC curve was at least as large for the IML as for the CAP, reflecting in part the more extensive working range of the IML (0.10-100 kIU/L vs 0.35-100 kIU/L for CAP). CONCLUSION: Laboratory testing for sIgE can be performed on a fully automated, random-access system with an extended working
range and with diagnostic accuracy for representative allergens equivalent to or better than that of the semiautomated CAP technology.

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