SSAI Société Suisse d'Allergologie et d'Immunologie
Schweizerische Gesellschaft für Allergologie und Immunologie
Swiss Society for Allergology and Immunology

Reporting of total IgE and allergen-specific IgE test results in Switzerland: Recommendations of the Swiss Society for Allergology and Immunology (SSAI) - Commission on Laboratory Diagnostics (CLD)

September 30, 2021

Revision of "Recommendations to report allergen-specific IgE" (December 11, 2020)

Following a survey conducted by the Commission of Laboratory Diagnostics (CLD) in October 2019 it appeared that the way of reporting total IgE as well as allergen-specific IgE is very different from one laboratory to another.

The survey consisted on a questionnaire distributed to all laboratories participating in the external quality assessment schemes on IgE testing in Switzerland (i.e., MQ and CSCQ), representing doctor's offices, commercial as well as non-university hospitals and university hospitals laboratories. A total of 24 laboratories responded.

The variability in reporting of results may have an impact on the interpretation of these results by health professionals. This prompted the CLD to issue recommendations to harmonize the way of reporting IgE results.

Total IgE

Six different assays are used for total IgE quantification by the responding laboratories. The units used when reporting total IgE concentration vary among the different laboratories. In addition, the reference values, when they are reported, are highly different.

Recommendation:

1. In case the assay is calibrated against the WHO current 11/234 or previous 75/502 International Reference Reagents, total IgE values are to be reported in IU/mL or kIU/L. Although these units are equivalent, we recommend -to avoid confusion- reporting in kIU/L.

The establishment of age-specific reference intervals for both children and adults has been documented by several studies, but substantial differences between these studies hamper to define uniformly valid values (1-3). Therefore, no recommendations on reference values are given here. Each laboratory should check the transferability of the available reference values for its own patient group and, if necessary, determine its own intervals.

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Allergen-specific IgE

Five different assays are used for allergen-specific IgE quantification by the laboratories participating in the survey. Similar to total IgE reporting, a large variability also exists in the units used for reporting allergen-specific IgE. Furthermore, laboratories, including those that use the same assay, report down to different quantitative values. The historical cutoff of 0.35 kUA/L is commonly employed as a reference value by laboratories using the ImmunoCAP® Specific IgE assay, whereas laboratories using other assays use different reference values. Results above the reference value are flagged by the majority of laboratories.

Recommendations:

2. Results of allergen-specific IgE are to be expressed in the arbitrary units of the assay, exactly as indicated by the manufacturer of the assay (e.g., kU_A/l (or kUA/l) for ImmunoCAP® Specific IgE and ALEX®; ISU-E for ISAC®).

3. The assay used for measuring specific IgE should be listed on the laboratory report so the medical professional can determine which published disease-predictive algorithms to use for the interpretation of the reported results (4).

4. Allergen-specific IgE results should be reported quantitatively as continuous measures down to the lower limit of quantification of the assay (e.g., 0.1 kUA/l for ImmunoCAP® Specific IgE; 0.3 kUA/l for ALEX®; 0.3 ISU-E for ISAC®) (4).

5. There is no single cutoff point for specific IgE that discriminates between negative and positive sensitization that can be extrapolated to all allergens. Specific IgE levels should be interpreted with a probabilistic approach, and it is thus recommended not to show reference values for specific IgE (4, 5).

6. Allergen-specific IgE results should not be reported in the historical and arbitrarily defined "classes" as this is no longer considered clinically useful (4).

7. When reporting allergen-specific IgE results, neither the tests nor the results should be referred to as "allergy tests". The term "allergy tests" for specific IgE tests is misleading and holds a great source of misinterpretation since patients regarding IgE sensitization tests as allergy tests generally self-translate results into clinical diagnosis (5, 6).

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