

## Evaluation of a Particle-enhanced Turbidimetric Immunoassay for the Measurement of Immunoglobulin E in an ILab 900 Analyzer

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**Background:** The measurement of immunoglobulin E (IgE) in serum is widely used in the diagnosis of allergic reactions and parasitic infections. We describe here a fully automated assay for human IgE suitable for routine application in a general chemistry analyzer.

**Methods:** We used an ILab 900<sup>®</sup> analyzer. This instrument automates a particle-enhanced immunoturbidimetric assay with an analysis time of 9 min.

**Results:** The assay was linear in the range 4–1000 kIU/L ( $r = 0.9998$ ). The intra- and interassay CVs at 57, 235, and 434 kIU/L were <3.5% and <7.4%, respectively. The detection limit was 4 kIU/L. Hemoglobin ( $\leq 16$  g/L), bilirubin ( $\leq 250$   $\mu$ mol/L), and myeloma paraproteins did not interfere with the assay. The assay showed good correlation with a microparticle enzyme immunoassay ( $r = 0.998$ ) with a mean difference between methods of  $-6 \pm 26$  kIU/L.

**Conclusion:** The new automated serum assay for IgE is an attractive alternative that avoids the need for dedicated instrumentation.

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Immunoglobulin (Ig)<sup>E</sup> is an antibody involved in the reactions of allergic disease and parasitic infections (1). Several methods for measuring total serum IgE have been reported. These include competitive binding assays (2), ELISA (3), microparticle enzyme immunoassay (MEIA) (4), and time-resolved fluoroimmunoassays (5). These methods fulfill the rigorous requirements for sensitivity and specificity that permit the detection of microgram per liter concentrations of IgE even in the presence of gram per liter concentrations of IgG, IgM, and IgA. However, they are often time-consuming and need special, often dedicated, instruments. Conversely, turbidimetric immu-

noassay is a well-established technique for the rapid quantification of analytes at gram per liter concentrations (6) and is widely used for the measurement of immunoglobulins other than IgE. The concentration range for turbidimetric assays may be extended by using the light-scattering properties of the immunoaggregates obtained by attaching the antibody to latex particles, termed particle-enhanced turbidimetric immunoassay (PETIA) (7–10). These techniques do not require specific instruments, merely a general automated analyzer, and have the advantages of decreased operating time and reduced costs together with an overall integration with other clinical chemistry analyses. Here we describe a PETIA for the measurement of IgE adapted for use in an ILab<sup>®</sup> automatic analyzer, and compare it with a well-established MEIA.

### Materials and Methods

#### APPARATUS

IgE measurements were performed in an ILab 900, an automated, random-access, discrete clinical chemistry analyzer (Instrumentation Laboratories). This instrument facilitates the performance of spectrophotometric and turbidimetric reactions at 37 °C, using one or two reagents, in bar-code primary tubes. Up to 50 different techniques can be processed simultaneously on-line in the same sample. For comparison studies, we used the MEIA technique from Abbott Diagnostics in an IMx<sup>®</sup> immunoassay automatic analyzer (Abbott). The analyzer is a batch immunoassay system capable of producing 40 results per hour following an initial delay of 30–50 min. The MEIA technique is a type of enzyme immunoassay in which the sample reacts with antibody-coated latex microparticles; after incubation at 34 °C, the bound and unbound components are separated using a glass-fiber matrix (11).

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Received March 9, 1999; accepted June 4, 1999.

<sup>®</sup>Nonstandard abbreviations: Ig, immunoglobulin; MEIA, microparticle immunoassay; and PETIA, particle-enhanced immunoturbidimetric assay.

# Ilab 900 Manual

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