Immunochemistry System

**Total Immunoglobulin E (IGE)**

**Clinical Significance**

IgE is a member of the immunoglobulin family of proteins that was first described in the 1960's. IgE, like all immunoglobulins, is produced by plasma cells in response to antigenic stimuli. However, IgE is unique in certain structural aspects and the role it plays in allergic diseases.

Measurement of total serum IgE is often used as a tool in the diagnosis and management of atopic diseases such as asthma, hay fever, atopic dermatitis and urticaria. It has been used to distinguish atopic from nonatopic individuals presenting allergy-like symptoms. In addition, studies have also shown that increased levels of IgE in cord blood and infants may be predictive of future atopic tendencies.

Normal levels of circulating IgE are extremely low in comparison to other immunoglobulins. Levels of IgE at birth are almost undetectable but increase in non-allergic adults. Elevated levels are commonly seen in cases of allergic diseases, parasitic infections, pulmonary aspergillosis, Wiskott-Aldrich Syndrome, and myeloma.

Serum IgE levels may vary as a result of diet, genetic background, geographical location and other factors. It is therefore recommended that the total IgE measurements be used in conjunction with other tests when establishing diagnosis.

**Intended Use/Methodology**

Beckman Coulter's IGE (Total Immunoglobulin E) reagent is intended for the quantitative determination of total human immunoglobulin E (IgE) in serum or plasma by rate turbidimetry. An anti-IgE antibody coated particle binds to IgE in the patient sample resulting in the formation of insoluble aggregates causing turbidity. The rate of aggregate formation is directly proportional to the concentration of IgE in the sample.

**Product Information**

The IGE reagent, when used in conjunction with the IMMAGE Immunochemistry System and IGE Calibrator, is intended for the quantitative determination of total human IgE by rate turbidimetry.

The easy-to-use IMMAGE requires no sample preparation and provides results in just a few minutes. The IMMAGE tests offer:

- Liquid, ready to use reagents
- Single point calibration verification
- 30-day calibration stability
- IGE calibrator conveniently packaged with reagent kit
- Up to 24 months stability when stored properly
- Accepts ultracentrifuged lipemic samples
Product Specifications

**PRINCIPLE**
Near Infrared Particle Immunoassay (NIPIA)

**SENSITIVITY**
5 IU/mL

**MEASURING RANGE**
5 to 30,000 IU/mL

**SAMPLE TYPE**
Serum or Plasma

**PRECISION**
≤ 7.0% within-run
≤ 7.5% total

**STABILITY**
Up to 24 months when stored properly

**CALIBRATION STABILITY**
30 days

**SAMPLE VOLUME**
20 uL

**INTERFERENCE**
The reaction is not affected by:
- Bilirubin ≤ 60 mg/dL
- Lipid (Human Triglyceride) ≤ 1,600 mg/dL
- Hemoglobin ≤ 750 mg/dL
- Rheumatoid Factor ≤ 660 mg/dL

**Ordering Information**
474620 Reagent and Calibrator (packaged together)
Includes: 150 tests and 2mL of calibrator.

**Reference**