CE

Product Description Total IgE

Product and Process Description

Determination of total immunoglobulin E (IgE) is based on the principle of an enzyme immunoassay (EIA) for quantitative analysis of total IgE in serum or plasma. Total IgE determination performed with this testing kit is only validated in combination with BDL testing system und must not be performed with other systems, because investigated performance data have been validated especially for BDL testing systems. Testing application is restricted to qualified personnel that are specially trained in applying IVD operations.

IgE is a serum protein and main carrier of reagin activity of allergic type I reactions (immediate-type allergy).
IgE circulates in blood stream; being responsible for clinical symptoms of type I reactions IgE binds to the surface of mast cells and basophilic granulocytes. Attachment occurs through the Fc part of IgE molecules. Allergen contact with corresponding (specific) IgEs leads then to release of pro-inflammatory mediators and hormones (e.g. histamine).

The BDL Total IgE test measures the entity of all variants of IgEs in serum or plasma and represents thus a collecting test, which indeed displays support for interpretation of diagnostic results, but does not give evidence for sensitisation against distinct allergens. Therefore results of total IgE testing in serum should be only a part of a diagnosis concept which consists of accurate anamnesis, skin prick test and provocation test as well as other *in-vitro* assays.

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Total IgE

Quantitative determination of circulating total IgE results from a non-competitive enzyme immunoassay.

Solid phase consists of a microwell cavity which surface is coated with an anti-IgE antibody. First operation step contains pipetting of patient serum or plasma into the cavity. As second step an enzyme-linked anti-human IgE is pipetted into the cavity. These steps allow simultaneous binding of total IgE to solid-phase adsorbed anti-IgE and between the enzyme-linked anti-human IgE to total IgE. Unbound serum and unbound linked anti-human IgE are removed by a washing step. The amount of bound enzyme-linked anti-human IgE is proportional to the amount of total IgE in serum / plasma. Next operation step includes addition of substrate solution (p-nitrophenyl phosphate, p-NPP). Caused by the activity of the linked enzyme (alkaline phosphatase) substrate is processed and a coloured solution develops. Enzyme reaction is abandoned via addition of stopping solution at the end of incubation time. Extinction is investigated by photometric measurement. Data analysis is performed by using a standard curve consisting of extinction values of measured standard cavities. Figure 1 illustrates all operation steps and underlying molecular background.

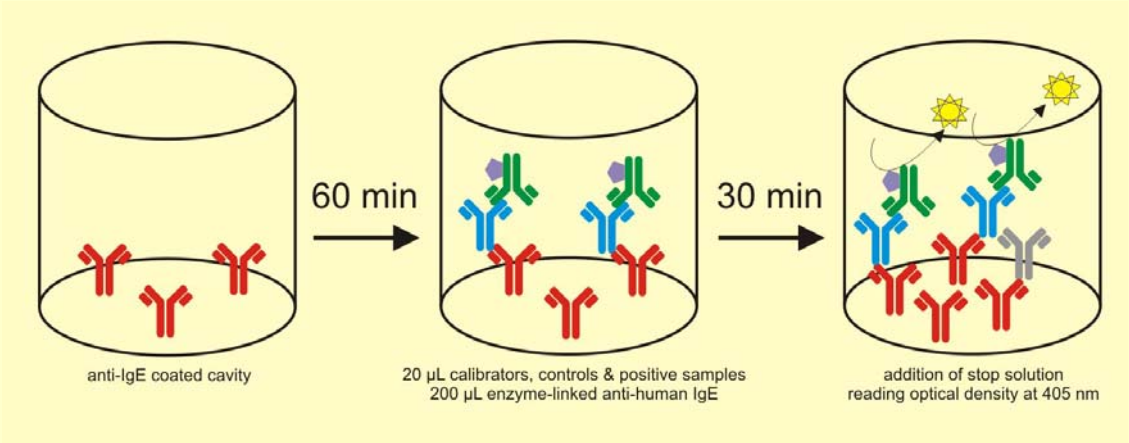

Fig.1: Total IgE assay procedure

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Assay Limitations

Reliable and reproducible results can only be received in terms of a testing procedure corresponding to product specifications.

In case of using several microwell cavities in one test, incubation times of individual plates must be considered.

Clinical diagnose should not be exclusively based upon the detection of increased or decreased total IgE levels, but also include other clinical data and testing results. The *in-vitro* determination of total IgE should never be the exclusive diagnostic basis of decision-making for starting a hyposensitisation or similar therapy. In addition skin prick tests, other *in-vitro* tests (e.g. specific IgE) and if procurable also provocation tests to prove clinical relevance must be performed.

Negative or low total IgE results can occur if:

- symptoms are not IgE mediated
- sample was taken before organism could generate antibodies against allergen
- IgE level could regenerate after long period of sensitisation
- IgE consumption due to allergic reaction

Identical results of different patients do not come along with the same reaction basis because of individual difference.

Positive results in total IgE *in-vitro* tests may not mandatorily be accompanied by

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clinical manifestations.

Increased total IgE values can indicate an atopic disposition. In special cases total IgE determination can be consulted as additional diagnosis of atopy-associated diseases (e.g. farmer´s lung, vasculitides, etc.) as well as inherent and acquired immunodeficiency (Hyper-IgE-Syndrom or T-cell defects).

Related to specific IgE determination total IgE serves as additional parameter for evaluation of specific IgE titers. However total IgE analysis cannot detect or exclude specific sensitisation. For atopy screening total IgE determination is limited.

Production procedure

Manufacturing of all components belonging to the testing system follow validated standard operation protocols and underlie strict quality guidelines implemented by BDL Labordiagnostik GmbH in accordance with current authority requirements. Every component passes appropriate quality controls before approval.

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