

## Order references

### Reagents

REF		CONT
IEDGX-B00	Universal kit	1 x 20 ml R1 + 1 x 10 ml R2
IEDGX-H00	Universal kit	2 x 30 ml R1 + 2 x 15 ml R2

### Other necessary products

REF		CONT
IEREK-000	IgE Calibrators Kit (5 Levels)	5 x 1 ml
IECOS-003	IgE Low Control	1 x 3 ml
IECON-003	IgE Medium Control	1 x 3 ml

## Field of application - Purpose

In vitro diagnostic reagent for the quantitative determination of immunoglobulin E in samples of human origin by immunoturbidimetry on photometric systems.

## Medical benefit - Scientific validity

Human Immunoglobulin E (IgE) is a protein with a molecular weight of 190,000 daltons. It is composed of two heavy chains and a pair of light chains linked together by disulphide. A function of IgE is the immunity to parasites. In industrialized countries, IgE has also an important role in allergic reaction (type I hypersensitivity) such as asthma, dermatitis and food allergies. Elevated IgE levels in human serum are also observed in atopic diseases, rare myeloma and disorders related to T cell dysfunction (AIDS for example). IgE levels measurement in serum is mainly useful in the diagnosis, following and treatment of atopic diseases and parasitic infections.

## Method principle

The latex particles are stabilized in colloidal form with anti-immunoglobulin E antibodies specifically directed against the immunoglobulin E. The reaction of these particles with the immunoglobulin E, present in a biological sample, causes specific agglutination of the latex particles. This agglutination, directly proportional to the immunoglobulin E concentration of the sample, is read at 570 nm and 800 nm.

## Warning and precautions

- For in vitro diagnostic use only.
- Must be handled by qualified personnel under the responsibility of a biologist.
- The human-origin products have been screened and found negative for HIV 1 and 2 antibodies, HCV antibodies and HBAg, but they must nevertheless be handled as potentially infectious products.
- These products contain sodium azide. Products containing sodium azide must be handled with care: avoid ingestion and contact with the skin or mucous membranes.
- Sodium azide becomes explosive on contact with heavy metals such as copper or lead.

## Samples

### Collection conditions

Collect specimens using standard laboratory techniques; use only suitable procedures, tubes or collection containers.

### Sample type

Serum and plasma

### Storage and stability of specimens

Temperature	Stability
-20 °C	≤ 6 months
4-8 °C	≤ 7 days
20 - 25 °C	≤ 7 days

This information comes from data originating from “Tietz Clinical Guide to Laboratory Tests” and from “WHO”.

## Reagents

### Composition and concentrations/Storage

Active ingredients:

Reagent R1: none.

Reagent R2: Suspension of latex colloidal particles coated with anti-human IgE antibody.

Other ingredients:

Reagent R1: buffer, stabilising agent, inorganic salt and preservative.

Reagent R2: buffer, stabilising agent, polystyrene, inorganic salt and preservative.

Storage temperature:

Reagent R1: 2 - 8°C.

Reagent R2: 2 - 8°C

### Preparation

Ready to use.

### Storage and stability

Reagents are stable until the expiration date printed on the packaging (months passed), under the following recommended storage and handling conditions:

- Unopened vial stored at temperature indicated on packaging.
- Opened vial: closed immediately after use or placed on closed analyser intended for this purpose, not contaminated by handling and stored at the temperature indicated on the packaging.

Note:

- Do not freeze the reagents.
- Nanoparticle-based reagents can settle over time. It may be necessary to delicately mix by repeated turning.

### Other materials required

Usual laboratory equipment including an analytical system equipped with a photometric detector.

## Calibration

### Calibration

The calibration curve is performed by using the calibration kit indicated in the “Order references” section. The zero point of the calibration curve is performed with physiological saline solution.

## Traceability

The method has been standardised with a benchmark method traceable to the international standard as described in the associated calibrators data sheet (see the “Order references” section).

Calibrate the method when the reagent batch number changes or in case of change in performance (contact the manufacturer if the changes persist) or if quality control requires it.

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## Quality control

The frequency of controls and the confidence limits must be adapted to the laboratory requirements. The results must be within the defined confidence limits. Each laboratory shall establish corrective measures to be taken if results fall outside the defined limits. Comply with current legislation in the country and local guidelines relating to quality control.

The calibration curve and its stability can be validated using the control materials indicated in the “Order references” section.

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## Reference values

	Reference values
Newborns	< 1,5 UI/ml
< 1 year	< 15 UI/ml
1 – 5 years	< 60 UI/ml
6 -9 years	< 90 UI/ml
10 – 15 years	< 200 UI/ml
Adults	< 100 UI/ml

International units: UI/ml

Conventional units: UI/ml

This information comes from data originating from “Tietz Clinical Guide to Laboratory Tests” and from “WHO”.

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## Analytical performances

The analytical performance data below are given as an indication. The results obtained in the laboratory may differ from these.

The analytical performances were determined following the indications of the “Guide technique d’accreditation de vérification (Portée A)/validation (Portée B) des méthodes en biologie médicale”; document SH GTA 04 Révision 01.

### Measurement range

21,0 - 1436 UI/ml

The measurement range is bounded by the quantification and linearity limits. Samples having a concentration greater than the upper limit must be diluted.

### Limit of detection

8,7 UI/ml

It is the smallest signal expressed as a quantity or concentration that can be distinguished with a given probability from a reagent blank performed in the same conditions.

The evaluation of the limit of detection is based on the statistical analysis of the observed signal differences between the blanks and samples.

### Interferences (Analytical specificity)

There is no known cross-reactivity of the antiserum cited or the antibodies used.

The abnormally coloured and particle-containing samples can cause, depending on the analytical system, assay errors. These samples must be clarified chemically or physically before their assay.

## Precision

The precision is evaluated using the repeatability (CV within-run) and reproducibility (CV within-calibration).

	Repeatability (n=30)		Reproducibility (n=30)	
	Average (UI/ml)	CV (%)	Average (UI/ml)	CV (%)
Level 1	67,6	1,39	77,7	7,43
Level 2	193,0	0,77	207,8	3,26
Level 3	522,4	0,76	553,7	2,21

## Trueness - Accuracy

Trueness, quantified by the bias, is estimated by comparing the mean obtained in the intermediate precision study, based on internal quality control samples, with the expected target value equated to the “true” value of the tested sample.

Accuracy is defined as the closeness of agreement between a measured value and a true value of a measurand (quantity to be measured).

DiAgam allows a bias of 5% compared to the international standard or compared to a reference method traceable to the international standard when it exists.

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## Limitations of the method

The results of this test should always be interpreted in relation to the patient’s medical history, clinical signs and other findings.

### Prozone

By limiting the linearity to the value of the upper limit of the measurement range, no excess antigen effect was observed for samples with a concentration up to 13500 UI/ml.

### Matrix effect

The inter-laboratory control samples and controls can yield different results from those obtained with other assay methods because of a matrix effect. In this case, an analysis of the results according to specific target values of the method utilised may be necessary. If in doubt, contact the manufacturer.

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## Utilisation procedure






















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## Literature

1. Tietz Textbook of Clinical chemistry and molecular Diagnostics, fourth edition, edited by Carl A. Burtis, Edward R. Ashwood, David E. Bruns, 2006
2. Use of Anticoagulants in Diagnostic Laboratory Investigations & Stability of blood, plasma and serum samples. Publication WHO/DIL/LAB/99.1 Rev. 2. Jan. 2002.
3. Clinical guide to laboratory tests, second edition, edited by Norbert W. Tietz, 1990
4. CLSI. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Sixth Edition. CLSI document H3-A6 (ISBN 1-56238-650-6). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; 2007.
5. NCCLS. Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard-Fifth Edition. NCCLS document H4-A5 [ISBN 1-56238-538-0]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004.

## Symbols legend

The following symbols may appear on the packaging and the label:

	Batch code		Buffer
	Use until		Calibrator
	Manufacturer		High
	In vitro diagnostic medical device		Moderate
	Temperature (Storage at)		Low
	Catalogue reference		4 levels
	Read the usage instructions		5 levels
	Reagent		6 levels
	Kit		Control
	Content		This product meets the requirements of European Directive 98/79 EC concerning in vitro diagnostic medical devices
	Antibody or Antisera		

	<p>DiAgam Belgium: Rue du Parc Industriel 40, 7822 Ghislenghien, Belgium</p> <p>Avenue Louis Lepoutre 70, 1050 Bruxelles, Belgique</p> <p>DiAgam France: Boulevard de la Liberté 130, 59000 Lille, France</p>
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