# Immunoglobulin E Low Control

✓ ***REFERENCE***

| IgE Low Control | IECOS-003 | 1 x 3 ml | 2-8 °C |
|---|---|---|---|
| Immunoglobulin E control is a pooled human serum standardized from the reference WHO 11/234. | | | |
| Batch number : | | **21F23** | |
| Expiry date : | | **05/2023** | |
| Control date : | | **24/06/21** | |
| Control report number : | | DGM-QAC-REP-**21148** | |
| Document prepared and signed by : | | **L.Ginneberge** | |

✓ ***SAMPLES AND REFERENCE VALUES***
See the corresponding reagents technical sheet.

✓ ***COMPOSITION***
Immnunoglobulin E control is a pooled human serum. Stabilizers are added before lyophilisation.

✓ ***PRINCIPLE OF TEST***
The latex particles in colloidal form are stabilized with anti-IgE antibodies directed specifically against IgE. The reaction of these particles with IgE, present in a biological sample, causes the specific agglutination of the latex particles. This agglutination is directly proportional to the IgE concentration of the sample.

✓ ***PRECAUTIONS***
For in vitro single diagnostic use. To be handled by entitled Personnel.
Products from human source were tested and found free from HBsAg and antibodies to HCV and HIV but this material should be treated just as carefully as potentially infective.
Products containing sodium azide have to be handled with care ; avoid ingestion and contact with skin and mucous membranes. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.

✓ ***ANALYTICAL PERFORMANCES***
See the corresponding reagents technical sheet.

✓ ***PREPARATION AND REAGENTS STABILITY***
The control has to be stored in unopened vial at 2-8°C.The control is lyophilized and has to be reconstituted before use with 3 ml of distilled water; swirl gently and let stand undisturbed for 30 minutes at room temperature. Do not invert vial or mix vigorously. Gently mix contents before each use. Once proper reconstituted, it is stable for 2 weeks at 2-8°C in capped vial.

✓ ***METHOD OF ANALYSIS AND CALCULATION***
See the corresponding reagents technical sheet.

✓ ***QUALITY CONTROL***
Accuracy and reproducibility: Accuracy and reproducibility: analytical performances can be checked with the internal quality control serum of the laboratory.

✓ ***BIBLIOGRAPHY***
Use of Anticoagulants in Diagnostic Laboratory Investigations & Stability of blood, plasma and serum samples. Publication WHO/DIL/LAB/99.1 Rev. 2. Jan. 2002.

CE

IECOS 21F23 IFU EN v01 25/08/21

| | CONTROL IU/ml | |
|---|---|---|
| | **Target** | **Range** |
| **Immunoglobulin E** | **78.3** | **62.6 – 93.9** |

*Values assigned from the reference WHO11/234.*

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***Symbols***

The following symbols may appear on the packaging and labelling :

| | | | |
|---|---|---|---|
| LOT | *Batch code* | BUF | *Buffer* |
|  | *Use by* | CAL | *Calibrator* |
|  | *Manufacturer* | H | *High* |
| IVD | *In Vitro Diagnostics Medical Device* | M | *Medium* |
|  | *Temperature limitation (store at)* | L | *Low* |
| REF | *Catalogue number* | 4 LEV | *4 levels* |
|  | *Consult instructions for use* | 5 LEV | *5 levels* |
| REAG | *Reagent* | 6 LEV | *6 levels* |
| KIT | *Kit* | CONTROL | *Control* |
| CONT | *Contents* | CE | *This product meets the requirements of European Directive 98/79 CE concerning diagnostic medical devices in vitro* |
| Ab | *Antibody or Antiserum* |  | *Track version changes* |

| | |
|---|---|
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