



Immunoglobulin E Control

✓ **REFERENCE**

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|--|-------------------|-----------------|--------------|
| Immunoglobulin E Control | IECON-003 | 1 x 3 ml | 2-8°C |
| Beta 2 Microglobulin control is a pooled human serum standardized from the reference WHO 11/234. | | | |
| Lot # | 19105 | | |
| Expiry date | 05/2021 | | |
| Control date | 08/01/2020 | | |
| Quality control report # | DGM-QAC-REP-19199 | | |
| Document prepared and signed by | L Ginneberge | | |

✓ **SAMPLES AND REFERENCE VALUES**

See the corresponding reagents technical sheet.

✓ **COMPOSITION**

Immunoglobulin 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.

✓ **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 properly 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.



IECONFTEEN 08/01/20 v00

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|-------------------------|----------------|--------------------|
| Immunoglobulin E | CONTROL | |
| | IU/ml | |
| | Target | Range |
| | 454,1 | 363,3–544,9 |

Values assigned from the reference WHO 11/234.