



IgE Immunoglobulins ITSL Turbidimetric Kit

Additional Information REF.: K.ITSL.IGE

PRODUCT DESCRIPTION

Name

Immunoglobulin E (IgE).

MANUFACTURING PROCESS

Latex Reagent

Latex + Antibody



Stabilization



Quality Control (first step)



Adding Stabilizers and Preservatives



Quality Control (final step)



Storage a little quantity of the Latex Reagent for Quality Control in a Real Time.

Buffer Reagent

Raw Materials Dissolution in DI Water



Adding Stabilizers and Preservatives



pH Adjust Required



Quality Control



Storage a little quantity of the Buffer Reagent for Quality Control in Real Time

Calibrators / Controls

Raw material (Certificate of Analysis)



Check the Concentration



Quality Control (first step)



Value Assignment



Quality Control (final step)

REAGENTS COMPOSITION

IgE Latex Reagent

Polystyrene particles (0.5 %) coated with rabbit antibodies anti-human-IgE in a neutral aqueous solution.

Preservative: sodium azide 0.075 %.

IgE Buffer Reagent

Phosphate buffer (0.1 M) containing NaCl (0.15 M), bovine serum albumin (0.5 %) and detergents.

Preservative: sodium azide < 1 g/L.

IgE Calibrators

Human - based reference fluid.

Preservative: sodium azide 0.075 %.

All raw materials of human origin used in the manufacture of this product showed no reactivity when tested for HBsAg, anti-HIV-1/2 and HCV with commercially available test methods. However, this product should be handled as though capable of transmitting infectious diseases

IgE Controls

Human - based reference fluid used for monitoring accuracy and precision in turbidimetric and nephelometric assays for IgE.

Preservative: sodium azide 0.075 %.

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CALIBRATION and CONTROL

Immunoglobulin E (IgE) Calibrators

The method was standardized against to WHO IRP 75/502.

Controls

The use of controls low and high is necessary for the validation of the calibration curve.

The values of the controls were calculated with own Reagents and Calibrators.

PRODUCT CHARACTERISTICS

Assay Precision

	<u>n</u>	<u>CV (41.0 IU/ml)</u>	<u>CV (80.8 IU/ml)</u>	<u>CV (139.2 IU/ml)</u>
Intra-assay	10	3.3 %	1.6 %	1.3 %
	<u>n</u>	<u>CV (41.0 IU/ml)</u>	<u>CV (80.8 IU/ml)</u>	<u>CV (139.2 IU/ml)</u>
Inter-assay	10	4.7 %	3.4 %	1.5 %

Results obtained using a Cobas Mira Plus Analyzer

Detection Limit

< 10 IU/ml (calculated as mean + 3 SD of the blank (n = 20))
Results obtained using a Cobas Mira Plus Analyzer

Blank Value

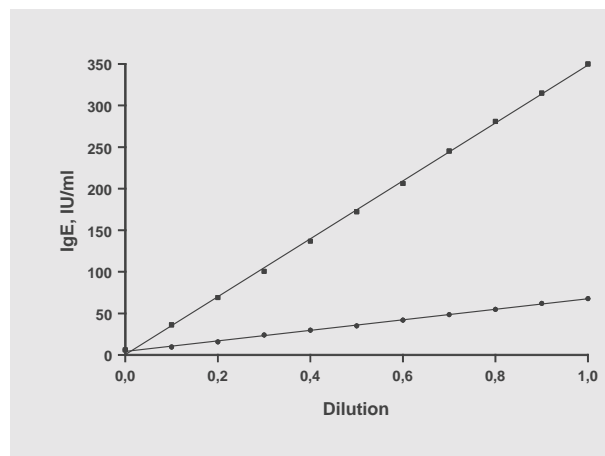
≤ 0.01 UA (Blank Value variation)
Results obtained using a Cobas Mira Plus Analyzer

Assay Range

0 - 900 IU/ml

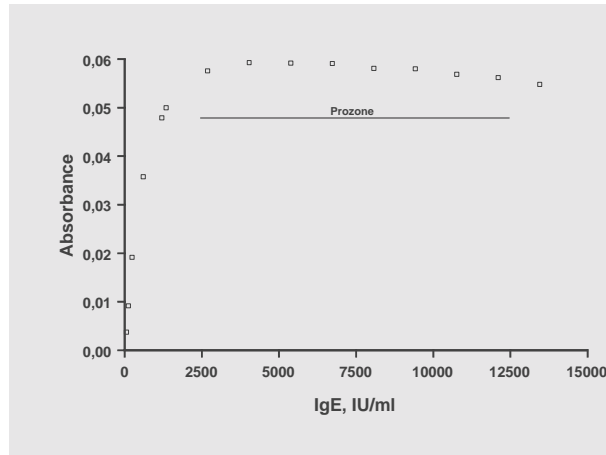
Linearity

Linearity was evaluated using serial dilutions, prepared with saline solution, of two different samples, which contained values of IgE in the range analysis. Within the assay's measuring range, the deviations of measurement from theoretical values did not exceed the 10 % level.



Prozone Phenomenon

The system did not show prozone phenomenon at least up to 12000 IU/ml.



Assay Sensitivity

< 10 IU/ml (Acceptability +/- 15%)

Results obtained using a Cobas Mira Plus Analyzer

Veracity

Method Comparison:

Reference Method: Chimioluminescence (ACS 180)

of Samples: 60

Analyzer Used: Cobas Mira Plus

$$y = ax + b$$

$$a = 0.9$$

$$b = 11.3$$

$$r = 0.996$$

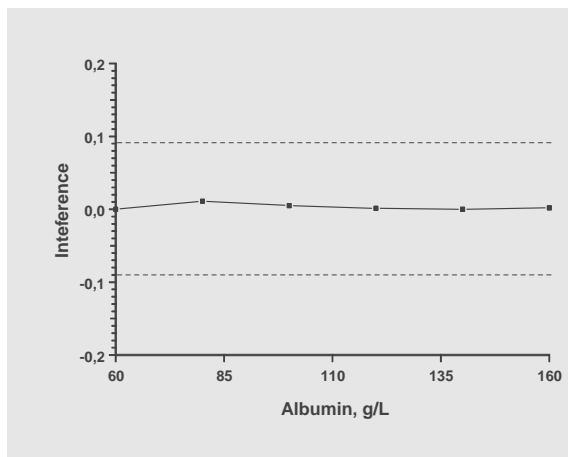


Specificity: Interferences

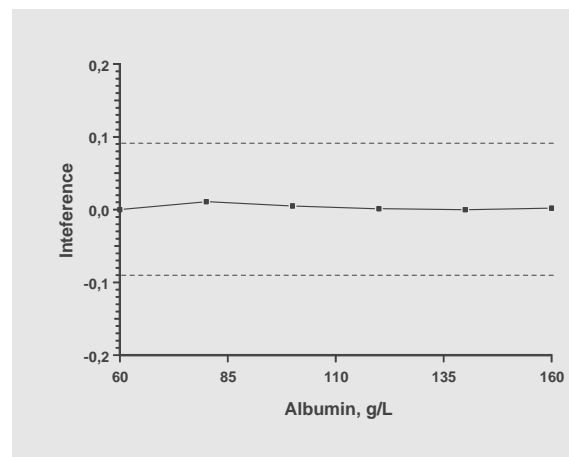
The horizontal lines show the tolerance for the value with interferent.
This values are: concentration without interferent $\pm 3 \times$ SD intra-assay.
Sample without interferent (m) and sample with interferent (m_i):

$$\text{Interference} = \frac{m_i - m}{m}$$

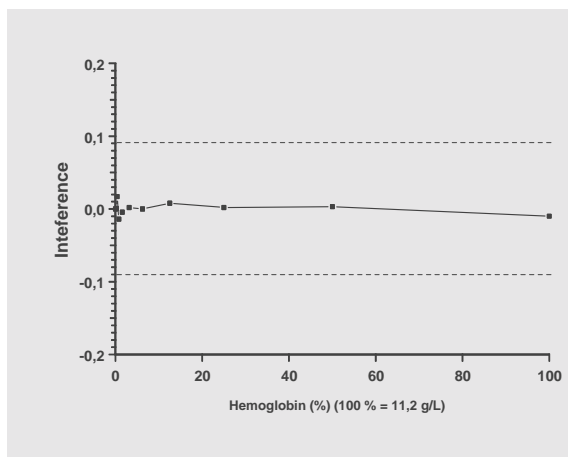
Lipemia



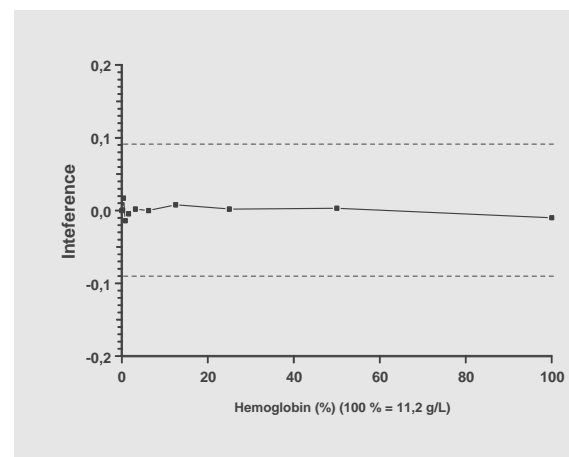
Proteins



Bilirubin

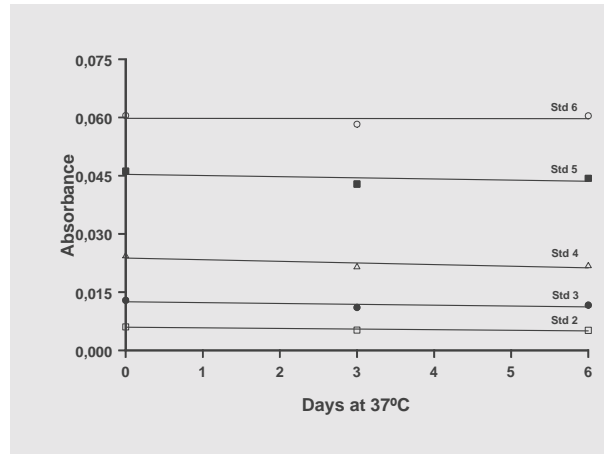


Hemoglobin



Stability - Stress Test

Absorbance variation of the calibrators for 6 days at 37° C



Microbiologic Control

Growth in Blood Agar (for 24 hours at 37° C) of reagents (stored at +2 - +8° C).

Buffer (age 32 months) => Negative

Latex (age 20 months) => negative