quantex IgE

CE

Kit Configuration

P/N 3000-2238 2 x 16 mL IgE R1
2 x 5 mL IgE R2

Reagent Preparation

P/N 3000-2238 IgE R1: Ready to use
IgE R2: Ready to use. Invert to mix well before first use. Avoid foam formation.
Place the bottles into reagent tray.

In Use Stability

For optimal stability remove reagents from the system and store them at 2-8°C in the original vial securely closed.
On board: 20 days

Specimen

Serum.

Calibration

Use quantex IgE standard multipoint Cat. No 3000-2240.See vial labels for lot specific concentrations. A reagent blank should be run daily before sample analysis. Recalibrate every 60 days or when a new lot of reagent is used.

Quality Control

Use quantex Ferritin/Myoglobin/IgE Control I/II Cat. No. 3000-2222.

Calculation of Analytical Results

The results concentration is automatically calculated by the instrument against the Calibration curve. For detailed description, refer to the Instrument settings and to the ILab 600/650 Operator's Manual.

Reference Interval

Age related concentrations must be taken into account when interpreting IgE values in children. IgE does not cross the placental barrier so IgE is not detectable in new borns. The IgE concentration increases during first years of life, reaching a peak at 10-15 years and dropping subsequently to adult values.

Age	1-12 months	1-5 years	6-9years	10-15years	Adults
Concentration (IU/ml)	<15	<60	<90	<200	<100

In any case, these concentrations are only indicatives and each laboratory should establish its own reference range.

References / Literatur / Bibliografía / Bibliographie / Bibliografia /

See package insert enclosed in the kit

Performance Characteristics

Limitation/Interfering Substances

No significant interference from bilirubin up to concentrations of 14.7 mg/dL (250 µmol/L) and hemoglobin up to concentrations of 1600 mg/dL (0.96 mmol/L). For a comprehensive review of interfering substances, refer to the publication by Young *et al.*[1]

Precision

	Samples/Runs	Mean (IU/mL)	CV(%)	Mean (IU/mL)	CV(%)
Within run	3/10	51.5	6.3	411	1.3
Total	3/10	51.5	9.6	411	2.2

Linearity

no rerun 30 -1000 IU/mL ; with rerun 10 - 10000 IU/mL

Instrumentation Laboratory

Instrumentation Laboratory SpA – V.le Monza 338 – 20128 Milano (Italy))
Instrumentation Laboratory Company - Lexington, MA 02421-3125 (USA)

quantex IgE

CE

Instrument Settings

Photometric Test Parameters		***Serum***
Test No.		**
Test Name, Test Code		IgE, IgE
Sample Type		Serum
Reporting Unit, Decimal Points		IU/mL, 0
Reation Cycle		Standard
Twin Analysis		OFF
Methodology Type, Measuring Point		End Point, 19/27
Photometric Methodology		1 Wavelength
Primary/Secondary Wavelenght		570
Sampling Conditions		
Sampling 1	Sample Vol.	4
	Sample/Diluent Vol.	0/0
Sampling 2	Sample Vol.	4
	Sample/Diluent Vol.	15/135
Sampling 3	Sample Vol.	12
	Sample/Diluent Vol.	0/0
Sampling 4		***
Diluent Code		Saline
Diluent Warning Limit		N/A
First Run		Sampling 1
Below/Above Normal Range		***
Panic L		Sampling 3
Panic H		Sampling 2
Noise		***
Prozone		N/A
High!, ABS!		Sampling 2
Sample Volume Reduction		**
Reagent Volumes		
R1	Code	01891
	Rgt/Dil. Vol. Stirring	160/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	20
R2	Code	01892
	Rgt/Dil. Vol. Stirring	80/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	20

Ranges and Evaluation Criteria	***Serum***
Normal Range-Male	**
Normal Range-Female	**
Normal Range-Other	**
Valid Range	0** - 1000
Hemolysis/Icterus/Lipemia Limit	***
Reaction Slope	Positive
Absorbance Limit	Above, 3200
Prozone Limit	N/A
Non Linear Limit	N/A
Slope/Intercept Correction	1/0
Qualitative Report	OFF
Calibration Conditions	
Calibration	6 Points, point to point, 2 Reps
Stability (days)	60
Calibrator, Concentration	IgE std, * (0 saline)
R-Blank Limit (mAbs)	2000
Cal. Reps Range (%)	***
Min Cal. Response (mAbs)	***
Cal. Factor Change (%)	***
M-Point Curve Fit (%)	N/A
Reagent Blank	ON
Auto R-Blank by Bottle	ON

* Lot dependent
** operator definable
*** optional
N/A not applicable to this test

Instrumentation Laboratory

Instrumentation Laboratory SpA – V.le Monza 338 – 20128 Milano (Italy))
Instrumentation Laboratory Company - Lexington, MA 02421-3125 (USA)