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.

Specimen

Serum.

Calibration

Use quantex IgE standard multipoint Cat. No 300-2240.See vial labels for lot specific concentrations. A reagent blank should be run daily before sample analysis. Recalibrate every 72 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 350 Operator 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	4/10	66	7.3	485	1.0
Total	4/10	66	11.9	485	3.0

Method Comparison

Comparison Method (x)	same reagent
Comparison Instrument (x)	Nephelometer (Behring BN II)
Slope	0.893
y intercept	-0.264
Mean X (IU/mL)	175
Mean Y (IU/mL)	156
r	0.994
n	102

Linearity

no rerun 25 -1000 IU/mL ; with rerun 25 - 1000 IU/mL

Minimun Detection Limit

18 IU/mL

Quantification Limit

25 IU/mL

Instrumentation Laboratory
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Instrument Settings

Chemistry Parameters				**R1**			
Method				**Reagent Name**	IgE	**Volume**	200 µL
Name	IgE			**R2**	enable		
				Reagent Name	IgE	**Volume**	80 µL
				Wash	disable	**Reagent Name**	
Unit	IU/mL					**Reagent Type**	
Assay Type	End			**Diluent**	enable	**Reagent Name**	Saline

Measuring Points	**1** enable	start	14	**Decimal Points**	0	
		end	14			
	2 enable	start	21	**Normal Range**	0	200
		end	21			
Wave Lenght						
Prim	570	**Sec**		**Technical Range (Conc)**	0.0	1000
				mAbs/10	-30000 / 30000	
Sampling Volume	5 µL					
Dilution	disable			**RPT Wash**	(R1)	Sys Water
	µL	µL			(R2)	Sys Water
Rerun (High)	5 µL					
Dilution	enable			**Instrument Factor a**	1	**b** 0
	15 µL	135 µL		**Stirring Speed**	R1 high	R2 high
Rerun (Low)	25 µL					

Calibration Checks

**	**Duplicate Limit**	**	mAbs/10	**Sampling Method for Standards**	
**	**Sensitivity Limit**	**	mAbs/10	x	Duplicate
					Tripicate
**	**Linearity Limit**	**	%		
				Blank measurement	
**	**Prozone Limit**	** upper		x	Enable Reagent blank
	SL1-S	** SL1-F **		None	
	SL2-S	** SL2-F **		**Reagent blank measurement at calibration**	
	Sens	**	mAbs/10	x	Reagent blank (system water)
x	**Absorbance Limit**			**	**Multiplex measurement is the same as standards**
	Reaction	Increase			
	Limit	25000	mAbs/10	**Reagent Blank Limit Checks**	
				**	Duplicate limit 50 mAbs/10

Calibration

Method		**Name**	IgE	**Interval**	72	**days**
Calculation	Point to Point					

	Conc	WORK	MASTER	Lot No
S1	0	-10		
S2	50	132		
S3	100	270		
S4	200	599		
S5	500	1983		
S6	1000	4639		

K N/A

Reagent Registration

Reagent Code	0189								
Reagent Name	IgE								
			Volume (L)		Volume (S)		Stability Check		Term	
R1	x	enable	**	mL	**	mL	x	enable	**	days
R2	x	enable	**	mL	**	mL	x	enable	**	days

** Operator definable N/A not applicable to this test Calibration curve is only as example

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