quantex TOXO

CE

Kit Configuration

P/N 3000-2181 2 x 14 mL TOXO R1
2 x 3.5 mL TOXO R2

Reagent Preparation

P/N 3000-2181 TOXO R1: Ready to use.
TOXO R2: Ready to use. Invert to mix well before first use.
Place the bottles into reagent tray.

In Use Stability

For optimal stability remove reagents from the system after use, and store them at 2-8°C in the original vial securely closed.

Specimen

Serum.

Calibration

Use quantex TOXO standard Cat. No 3000-2184. The calibrator concentration is indicated on the vial label. Instrument will perform auto dilution of standard (SS). A reagent blank should be run daily before sample analysis.

Quality Control

Use quantex TOXO Control Cat. No.3000-2185.

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.

Interpretation of results

Result	Interpretation
< 6 IU/mL	Negative
6-10 IU/mL	Doubtful
> 10 IU/mL	Positive

Concentrations of toxoplasma antibodies:

Under 6 IU/mL: Should be interpreted as absence of toxoplasma antibodies. If the serum tested corresponds to a pregnant woman, it is advisable to repeat the test during the pregnancy period (once every month) to detect a possible seroconversion.

Between 6 and 10 IU/mL: Should be interpreted as presence of toxoplasma antibodies at very weak level.

Over 10 IU/mL: Should be interpreted as presence of toxoplasma antibodies which may reflect either a past infection or an acute infection. In this case it is recommended to investigate the presence of specific IgM toxoplasma antibodies.

Reference Interval

See Package insert enclosed in the kit.

References / Literatur / Bibliografía / Bibliographie / Bibliografia /

See package insert enclosed in the kit

Performance Characteristics

Limitation/Interfering Substances

No interference has been observed in hemolyzed or icteric serum. Very lipemic or turbid samples should be clarified by high speed centrifugation before running the assay. To study possible interferences, samples with potential risk of producing cross reaction were tested, including sera positive for rheumatoid factor (RF), anti-nuclear antibodies (ANA) and from pregnant women. No evidences of interference were observed. 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	49.1	1.4	61.3	0.89
Total	3/10	49.1	1.4	61.3	1.2

Method Comparison

The quantex TOXO was studied in comparison to (MEIA) using a serum panel of 51 positive samples for IgG antibody, 15 positive samples for IgG and IgM antibodies, and 46 negative samples.
The relative sensitivity was 100%, the relative specificity was 97.7%, the positive predictive value was 98.6% and the negative predictive value was 100%.

Linearity

no rerun 5- 100 IU/mL ; with rerun 5- 1000 IU/mL

Quantification Limit

5 IU/mL

Instrumentation Laboratory

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

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Instrument Settings

Photometric Test Parameters		***Serum***
Test No.		**
Test Name, Test Code		TOXO, TOXO
Sample Type		Serum
Reporting Unit, Decimal Points		IU/mL, 1
Reation Cycle		Standard
Twin Analysis		OFF
Methodology Type, Measuring Point		End Point, 20/33
Photometric Methodology		1 Wavelength
Primary/Secondary Wavelenght		570
Sampling Conditions		
Sampling 1	Sample Vol.	15
	Sample/Diluent Vol.	0/0
Sampling 2	Sample Vol.	15
	Sample/Diluent Vol.	20/180
Sampling 3	Sample Vol.	30
	Sample/Diluent Vol.	0/0
Sampling 4		***
Diluent Code		Saline
Diluent Warning Limit		***
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	01631
	Rgt/Dil. Vol. Stirring	140/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	**
R2	Code	01632
	Rgt/Dil. Vol. Stirring	60/10, ON
	Low Vol. Warning Limit	***
	Stability (days)	**

Ranges and Evaluation Criteria	***Serum***
Normal Range-Male	**
Normal Range-Female	**
Normal Range-Other	**
Valid Range	0 - 100
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)	**
Calibrator, Concentration	Std TOXO, * 0 (saline solution)
R-Blank Limit (mAbs)	2200
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

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