

Kit Configuration

P/N 3000-2276	2 x 10.5 mL DIGI R1
	2 x 6.5 mL DIGI R2

Reagent Preparation

P/N 3000-2278: DIGO R1: Ready to use.
 DIGO R2: Ready to use. Invert to mix well before first use. Avoid foam formation
 Place the bottles into reagent tray.

In Use Stability

Stable until the expiration date shown on the vial when stored at 2-8°C. 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 DIGITOXIN standard multipoint Cat. No 3000-2284. The concentrations in µg/mL are indicated on the vial labels. Recalibrate every 7 days, when a new lot of reagents is used, when control recovery falls out of the expected range or when adjustments are made to the instrument. A reagent blank should be run daily before sample analysis.

Quality Control

Use quantex DIGITOXIN control I/II Cat. No 3000-2291.

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.

Therapeutic Range

The typical therapeutic range is 10 - 25 ng/mL (13 - 33 nmol/L) and the toxic range is > 45 ng/mL (> 59 nmol/L). To convert results to nmol/L multiply by 1.31.^{1,6}

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 20 mg/dL (340 µmol/L), hemoglobin up to concentrations of 1000 mg/dL (0.6 mmol/L) and lipemia up to concentrations of 20 g/L. For a comprehensive review of interfering substances, refer to the publication by Young *et al.*⁵

Precision

	Samples/ Runs	Mean (ng/mL)	CV (%)	Mean (ng/mL)	CV (%)
Within run	3/10	28.1	1.2	60.1	1.0
Total	3/10	28.1	3.3	60.1	3.1

Method Comparison

Comparison Instrument & Method (x)	MEIA/FPIA
Slope	1.039
y intercept	1.34
Range of x (ng/mL)	50 - 432
r	0.940
n	56

Linearity

no rerun 3.5 to 80 ng/mL
 With rerun 3.5 to 800 ng/mL

Instrument Settings

Photometric Test Parameters		Serum
Test No.		**
Test Name, Test Code		DIGI, DIGI
Sample Type		Serum
Reporting Unit, Decimal Points		ng/mL, 1
Reaction Cycle		Standard
Twin Analysis		OFF
Methodology Type, Measuring Point		End Point, 20/33
Photometric Methodology		1 Wavelength
Primary/Secondary Wavelength		700
Sampling Conditions		
<i>Sampling 1</i>	Sample Vol.	3
	Sample/Diluent Vol.	0/0
<i>Sampling 2</i>	Sample Vol.	3
	Sample/Diluent Vol.	15/135
<i>Sampling 3</i>	Sample Vol.	6
	Sample/Diluent Vol.	0/0
<i>Sampling 4</i>		***
Diluent Code		Saline
Diluent Warning Limit		***
First Run		Sampling 1
Below/Above Normal Range		***
Panic L		***
Panic H		Sampling 2
Noise		***
Prozone		N/A
High!, ABS!		Sampling 2
Sample Volume Reduction		**
Reagent Volumes		
R1	Code	01641
	Rgt/Dil. Vol. Stirring	105/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	**
R2	Code	01642
	Rgt/Dil. Vol. Stirring	65/10, ON
	Low Vol. Warning Limit	***
	Stability (days)	**

Ranges and Evaluation Criteria	Serum
Normal Range-Male	**
Normal Range-Female	**
Normal Range-Other	**
Valid Range	0 - 80
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 Repts
Stability (days)	7
Calibrator, Concentration	Digitoxin Std, *
R-Blank Limit (mAbs)	3500
Cal. Repts 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

