

**Kit Configuration**

P/N 3000-2329	2 x 12 mL MYO R1
	2 x 6 mL MYO R2

**Reagent Preparation**

P/N 3000-2329	MYO R1: Ready to use.
	MYO 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: 60 days.

**Specimen**

Serum.

**Calibration**

Use quantex MYOGLOBIN standard multipoint Cat. No 3000-2330. See calibrator insert sheet for specific concentrations. 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**

Myoglobin normal values can vary with age, sex and race. The upper limit for the reference interval (95th percentile) calculated for a group of healthy adult blood bank donors was 69 ng/mL. The upper limit for women (n = 181) was 43 ng/mL and for men (n = 175) was 76 ng/mL.

**References / Literatur / Bibliografía / Bibliographie / Bibliografia /**

See package insert enclosed in the kit

**Performance Characteristics**

**Limitation/Interfering Substances**

No significant interference from lipemia up to a sample absorbance of 16.6/cm at 660 nm ( up to 1300 mg/dL or 15 mmol/L triglycerides), bilirubin up to concentrations of 20 mg/dL (342 µmol/L), hemoglobin up to concentrations of 500 mg/dL (0.3 mmol/L) and rheumatoid factor up to 800 IU/mL. For a comprehensive review of interfering substances, refer to the publication by Young *et al.*<sup>1</sup>

**Precision**

	Samples/Runs	Mean (ng/mL)	CV(%)	Mean (ng/mL)	CV(%)
Within run	2/40	71.4	1.1	228.6	1.3
Total	2/40	71.4	1.9	228.6	2.3

**Method Comparison**

Comparison Method (x)	Nephelometric assay
Slope	0.994
intercept y	1.077
Range (ng/mL)	16 - 2070
Mean X (ng/mL)	261
Mean Y (ng/mL)	256
r	0.9985
Syx	12.2
n	67

**Linearity**

no rerun 10 - 500 ng/mL ; with rerun 10 - 5000 ng/mL

### Instrument Settings

<b>Photometric Test Parameters</b>		<b>Serum</b>
Test No.		**
Test Name, Test Code		MYO, MYO
Sample Type		Serum
Reporting Unit, Decimal Points		ng/mL, 0
Reaction Cycle		Standard
Twin Analysis		OFF
Methodology Type, Measuring Point		End Point, 21/33
Photometric Methodology		1 Wavelength
Primary/Secondary Wavelength		570
<b>Sampling Conditions</b>		
<i>Sampling 1</i>	Sample Vol.	12
	Sample/Diluent Vol.	0/0
<i>Sampling 2</i>	Sample Vol.	12
	Sample/Diluent Vol.	20/180
<i>Sampling 3</i>	Sample Vol.	***
	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		**
<b>Reagent Volumes</b>		
R1	Code	02901
	Rgt/Dil. Vol. Stirring	120/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	60
R2	Code	02902
	Rgt/Dil. Vol. Stirring	90/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	60

<b>Ranges and Evaluation Criteria</b>	<b>Serum</b>
Normal Range-Male	**
Normal Range-Female	**
Normal Range-Other	**
Valid Range	0 - 500
Hemolysis/Icterus/Lipemia Limit	***
Reaction Slope	Positive
Absorbance Limit	Above, 2400
Prozone Limit	N/A
Non Linear Limit	N/A
Slope/Intercept Correction	1/0
Qualitative Report	OFF
<b>Calibration Conditions</b>	
Calibration	5 Points, point to point, 2 Repts
Stability (days)	60
Calibrator, Concentration	Myoglobin Std, *
R-Blank Limit (mAbs)	1500
Cal. Repts Range (%)	***
Min Cal. Response (mAbs)	***
Cal. Factor Change (%)	***
M-Point Curve Fit (%)	N/A
Reagent Blank	OFF
Auto R-Blank by Bottle	ON

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