Myoglobin- turbilatex

Latex turbidimetry

Quantitative determination of Mioglobin (Mb)

IVD

PACKAGING

Ref.: 101-0475	Cont.: 1 x 24 / 1 x 8 mL

Store 2 - 8º C.

CLINICAL SIGNIFICANCE

Mioglobin is a hem-protein present in cardiac and skeletal muscle cells and is released into blood stream from these cells when they are damaged. The determination of serum Mb is effective in the diagnosis of myocardial infarction, muscular dystrophy, myositis and myopathy, and also for monitoring treatment progress and prognosis of the diseases. As early as 2-3 hours after unset of pain, myoglobin appears in high concentration in peripheral blood and, thus, can reach pathological values several hours before other biochemical makers do.

PRINCIPLE OF THE METHOD

The Mb-turbilatex is a quantitative turbidimetric test for the measurement of Mb in human serum or plasma. Latex particles coated with goat IgG anti-human Mb are agglutinated when mixed with samples containing Mb. The agglutination causes an absorbance change, dependent upon the Mb contents of the patient sample that can be quantified by comparison from a calibrator of known Mb concentration.

REAGENTS

Diluent (R1)	Glycine buffer 150 mmol/L, pH 8.3, Preservative.
Latex (R2)	Latex particles coated with goat IgG anti-human Mb, pH 7.3, Preservative.
Optional	Ref: 101-0476 Myoglobin Calibrator
Optional	Ref.:101-0477 Myoglobin Control

PREPARATION

Reagents: Ready to use.

CALIBRATION

The sensitivity of the assay has been standardized against an in-house Standard. It is not recommended the use of other commercially available Mb calibrators.

Calibration Curve: Prepare the following Mb calibrator dilutions in NaCl 9 g/L as diluent. Multiply the concentration of the Mb calibrator by the corresponding factor stated in table bellow to obtain the Mb concentration of each dilution.

Calibrator dilution	1	2	3	4	5
Calibrator (µL)	100	50	25	12.5	--
NaCl 9 g/L (µL)	--	50	75	87.5	100
Factor	1	0.5	0.25	0.125	0

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8º C and contaminations are prevented during their use. Do not use reagents over the expiration date.
Frozen Latex and Diluent could change the functionality of the test.

Reagent deterioration: Presence of particles and turbidity.

ADDITIONAL EQUIPMENT

- Thermostatic bath at 37ºC.
- Spectrophotometer or photometer thermostatable at 37º C with a 570 nm filter (560 – 580 nm).

SAMPLES

Fresh serum or plasma. Stable 7 days at 2-8º C or 3 months at –20º C.
The samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.

PROCEDURE

1. Bring the reagents and the photometer (cuvette holder) to 37º C.
2. Assay conditions:
   Wavelength : 570 nm (560-580 nm)
   Temperature : 37º C
   Cuvette ligth path : 1cm
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette:

	Blank	Calibrator /Sample
NaCl 9 g/L (µL)	25	--
R1 Diluent (µL)	750	750
R2. Latex (µL)	250	250
Calibrator o sample (µL)	--	25

5. Mix and read the absorbance against blank immediately (A_1) and after 5 minutes (A_2) of the sample addition.

Chronolab has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

CALCULATIONS

Calculate the absorbance difference (A_2-A_1) of each point of the calibration curve and blank:

$$(A_2\text{-}A_1)_{\text{calibrator / sample}} - (A_2\text{-}A_1)_{\text{blank}}$$

and plot the values obtained against the Mb concentration of each dilution. Mb concentration in the sample is calculated by interpolation of its $(A_2\text{-}A_1)_{\text{sample}} - (A_2\text{-}A_1)_{\text{blank}}$ in the calibration curve.

QUALITY CONTROL

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Chronolab Control Serum Mb is available (Ref.: 101-0477).
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

Up to 70 ng/mL. Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. **Linearity limit:** Up to 800 ng/mL, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in NaCl 9 g/L and retested again. The linearity limit and measurement range depends on the sample /reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
2. **Limit detection:** Values less than 10 ng/mL give non-reproducible results.
3. **Prozone effect:** Up to 24,000 ng/mL.
4. **Sensitivity:** Δ 1.0 mA. ng/mL.
5. **Precision:**

Intra-assay	(n = 10)		
Mean (ng/mL)	48.6	86.2	323.5
SD	2.3	3.3	3.8
CV	4.63	3.87	1.17

6. **Accuracy:** Results obtained using these reagents (y) were compared to those obtained using a TIA reagent (x). 55 samples were assayed. The correlation coefficient (r) was 0.999 and the regression line equation y = 0.980x – 2.105.

The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Hemoglobin (500 mg/dL), bilirrubin (60 mg/dL), triglycerides (1500 mg/dL), and rheumatoid factors (1000 IU/mL), do not interfere. Other susbstances may interfere[4].

NOTES

Clinical diagnosis should be not made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY

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