

## Quantitative determination of Myoglobin (Mb) IVD

Store 2 - 8°C.

### 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.

### CLINICAL SIGNIFICANCE

Myoglobin 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 onset of pain, myoglobin appears in high concentration in peripheral blood and, thus, can reach pathological values several hours before other biochemical makers do.

### REAGENTS

<b>R1</b>	Glycine buffer 150 mmol/L, pH 9.0. Sodium azide 0.95 g/L.
<b>R2</b>	Latex particles coated with goat IgG anti-human Mb, pH 7.3. Sodium azide 0.95 g/L.
<b>Saline Solution</b>	NaCl 9% (for samples predilution)
<b>Optional</b>	Ref.: ACC16-032 Mb Control.

### 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.

### PREPARATION

**Reagents:** Ready to use.

**Samples and Controls Pre-Dilution:** Before the use, samples and/or controls must be diluted in this way:

- 50 µL sample or control + 50 µL NaCl 9 g/L

**Working reagent:** Swirl the latex vial gently before use. Prepare the necessary amount following this dilution:

- 1 part R2 to 4 part R1 (1:4 dilution)

### STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°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

- Pipette 100 - 1000 µL
- Pipette 10 - 100 µL
- Cuvettes and microstirrers (ref. code ACC16-037)

### SAMPLES

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

### TEST PARAMETER

Filter: set the filter on position A  
Reading time: 300 seconds

### PROCEDURE

1. Pipette into an appropriate number of cuvettes:

kind of reagent	µL
Working reagent	500

2. Incubate the cuvettes in position 1-4 for at least 1 minute
3. Transfer each cuvette in the reading channel and, when requested on the display, add 50 µL of the pre-diluted sample or control
4. Read the result which will appear automatically on the reader's display after 300 sec.

### QUALITY CONTROL

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Vital Diagnostics Control Serum Mb is available (Ref.: ACC16-032).

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

### REFERENCE VALUES

Up to 65 ng/mL. Each laboratory should establish its own reference range.

### PERFORMANCE CHARACTERISTICS

1. **Linearity limit:** Up to 300 ng/mL, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in NaCl 9 g/L and re-tested 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 20 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:**

	Mean	SD	CV%
Intra-assay (n=10)	86.2	3.3	3.87

6. **Accuracy:** Results obtained using these reagents (y) were compared to those obtained using a nephelometric reagent (x). 37 samples were assayed. The correlation coefficient (r) was 0.994 and the regression line equation  $y = 1.520x + 2.076$ .

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

### INTERFERENCES

Hemoglobin (500 mg/dL), bilirubin (60 mg/dL), triglycerides (1500 mg/dL), and rheumatoid factors (1000 IU/mL), do not interfere. Other substances may interfere<sup>4</sup>.

### NOTES

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

### BIBLIOGRAPHY

1. Nemeth PM et al. J Histochem Cytochem 1984; 32: 1211-1216.
2. Isakov A et al. Arch Intern Med 1988; 148: 1762-1765.
3. Kallner A et al. Scand J Clin Invest 1989; 49: 633 - 639.
4. Singer JM et al. Amer J Med 1956; 21: 888
5. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

### PACKAGING

Ref.: ACC16-023	Cont.	: 1 x 24 mL R1
		: 1 x 8 mL R2
		: 1 x 50 mL Saline Solution