Bioway Chemistry Reagent Series

Myoglobin Reagent Kit

Detection of Myoglobin in Human Serum on Chemistry Analyzers

Cat. No. R046K11 ***Myoglobin Reagent Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

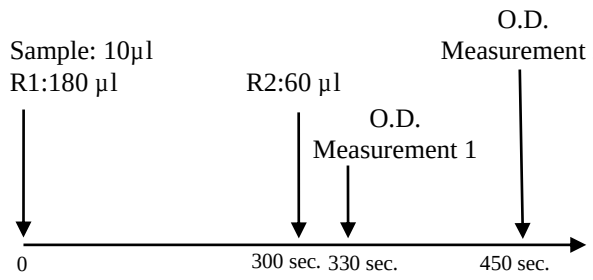

Table 1: Instrument Parameters*

Calibration method	5 point non-linear	Slope of reaction	increase
Wavelength	570nm/700nm	Sample volume	10 µl
Test method	2 point end	R1 volume	180 µl
Reaction temperature	37℃	R2 volume	60 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series **Myoglobin Reagent Kit** (the Kit) is a latex-enhanced immunoturbidimetric assay intended for *in vitro* quantitative detection of Myoglobin in human serum on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Myoglobin (Myo) is an iron and oxygen binding protein found in the muscle. It is found in the bloodstream only after muscle injury, in which the damaged muscle tissue releases high concentration of myoglobin into blood. This makes myoglobin a sensitive marker for muscle injury. Elevated Myo concentration in blood can be seen in acute myocardial infarction, acute muscle injury, muscular dystrophy, muscle atrophy, polymyositis, acute or chronic renal failure, severe congestive heart failure, long-term shock and other diseases.

TEST PRINCIPLES

The Kit utilizes latex-enhanced immunoturbidimetry to measure the Myo level in human serum. During the test, Myo in the sample binds with the antibody that is coated on latex particles to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer at wavelength of 570 nm. The change in absorbance is proportional to the level of Myo in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

MATERIALS PROVIDED

Reagents:

R1	Glycine Buffer solution, Bovine serum albumin
R2	latex particles coated with Myo antibody

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer.
2. Myo calibrator set (available for purchase) and control set (commercially available).

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8°C. Avoid direct sunlight. The Kit is stable for 12 month when stored properly. R1 and R2 reagents are stable for 1 month at 2-8°C after opening. Do not freeze the reagents.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
5. Reagents contain less than 0.1% sodium azide as preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum samples.
It is recommended to perform test immediately after sample collection to avoid hemolysis. If the test cannot be done immediately, store sample at 2- 8° C for 1 day or at -80° C for up to 1 months. Avoid repeated freezing and thawing.

TEST PROCEDURE (see Figure 1)

No pretreatment required for reagents and samples.

Calibration: 5 level calibrator set available for purchase. Recommend using Bioway calibrators for optimal results. Use multi-point non-linear calibration method.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 10 µl of sample and 180 µl of R1; mix well and incubate at 37°C for 300 seconds.
2. Add 60 µl of R2, mix well and incubate at 37°C for 30 seconds.
3. Take optical density measurement OD 1.
4. Take optical density measurement OD 2 at 450 seconds.
5. Calculate ΔOD = OD 2 – OD 1

RESULT

The Myo value can be obtained by using the calculated ΔOD to find the corresponding value on a calibration curve prepared with known values.

EXPECTED VALUES

21 ～100 ng/mL
It is recommended for each laboratory to establish its own expected values.

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QUALITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. Dilute sample with saline if measured value exceeds the linearity range. Calculate value by dilution factor.
3. Hemolysis samples may cause inconsistent results.
4. The test result from the Kit should not be used as the only basis for definite diagnosis.

PERFORMANCE CHARACTERISTICS

Linearity: 20 – 725 ng/mL ($R^2 \geq 0.990$)

Accuracy: relative deviation ≤ 20%

Precision: Within Run: CV≤6%;

Run-to-Run: CV≤10%

Interference: no interference detected for: Bilirubin (170 umol/L), triglyceride (11 mmol/L), and hemoglobin (3.0g/L).

Reagent Blank Absorbance: at 570nm wavelength and 10 mm optical diameter, O.D. ≤ 1.70.

Sensitivity: when measuring sample with 140 ng/mL Myo, ΔOD should be between 0.01 and 0.1.

REFERENCES

1.Mair J,Artner-Dworzak E, Lechleitner P, et al. Early diagnosis of acute myocardial infarction by a newly-developed rapid immunoturbidimetric assay for myoglobin. Br Heart J 1992;68:462-8

2.Mair P, Mari J, Seibt I, Balogh D, Puschendorf B. Early and rapid diagnosis of perioperative myocardial infarction in aortocoronary bypass surgery by immunoturbidimetric myoglobin measurements. Chest 1993; 103:1508-11

Not Intended for Sale in the United States.

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