Myo

Myoglobin (FIA)

infinosis™

REF: IN047702 Σ 25

Intended use
The Infinosis™ Myoglobin is a fluorescence immunoassay for the in vitro quantitative determination of Myoglobin (Myo) in Human whole blood, serum, or plasma. For professional use only.

Summary
References[1-5]
Myoglobin belongs to the globin superfamily of proteins, and as with other globins, consists of eight alpha helices connected by loops. Myoglobin contains 153 amino acids. Myoglobin is released from damaged muscle tissue (rhabdomyolysis), which has very high concentrations of myoglobin. The released myoglobin is filtered by the kidneys but is toxic to the renal tubular epithelium and so may cause acute kidney injury. It is not the myoglobin itself that is toxic (it is a protoxin) but the ferrihemate portion that is dissociated from myoglobin in acidic environments (e.g., acidic urine, lysosomes). Myoglobin is a sensitive marker for muscle injury, making it a potential marker for heart attack in patients with chest pain. However, elevated myoglobin has low specificity for acute myocardial infarction (AMI) and thus CK-MB, cardiac troponin, ECG, and clinical signs should be taken into account to make the diagnosis.

Test principle
Sandwich principle. Total duration of assay: **15 minutes**
Sample is added to the sample well of the test, then the fluorescence-labeled detector anti-myoglobin antibody binds to myoglobin antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and myoglobin are captured to anti-myoglobin antibody that has been immobilized on test strip.
The more myoglobin antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of myoglobin captured and instrument for infinosis™ tests shows myoglobin concentrations in blood specimen.

Reagents
Materials provided
- **Test Cartridge**, 25 pcs, individually packaged
- **ID chip**, 1 pcs
- **Sample Buffer,** 25 tubes
- **IFU**, 1 copy

Materials required (but not provided)
- infinosis™ 2020 FIA analyzer
- Myo control (DiaSino control is recommended)
- Transfer pipette set (100 µL size)
- Centrifuge (for plasma and serum only)
- Timer

Precautions and warnings
- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this instructions before testing.
- The test cartridge should remain in its original sealed pouch until ready to use. Do not use it if the pouch is damaged or the seal is broken.
- Do not use reagents beyond the labeled expiry date.
- Do not mix or use components from kits with different Lots.
- Don't use Test Cartridge if its Lot does not match with ID Chip that is inserted onto the instrument.
- The infinosis™ Myo should be used only in conjunction with the instrument for infinosis™ tests.
- The tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample is taken by qualified medical personnel.
- infinosis™ Myo assay is single use only. Do not reuse it.
- The Test Cartridge and instrument for infinosis™ tests should be used away from vibration and magnetic field. During normal usage, the Test Cartridge may generate slight vibration, which should be regarded as normal.
- Use separate clean pipette tips and buffer tubes for different specimens. The pipette tips and detector buffer tubes should be used for one specimen only.
- Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
- Blood specimens, used test cartridges, pipette tips and sample buffer tubes are potentially infectious. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
- The results should be interpreted by the physician along with clinical findings and other laboratory test results.

Incident report
Any suspected serious incidents related to this assay shall be immediately reported to DiaSino, DiaSino's Authorized Representative in the EU, and the national competent authorities of the Member States where the users and/or patients are located.

Storage and stability
- Store the test kit at 2-30℃, the stability is up to the expiration date printed on package.
- Test cartridge and sample buffer should be used within 1 hour after opening the pack.

Specimen collection and preparation
- The test can be performed with either whole blood, serum or plasma.
- Collect serum samples in accordance with correct medical practices.
- Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
- Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
- Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

Quality control
- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with infinosis™ tests. For more information regarding obtaining the control materials, contact DiaSino Laboratories Co., Ltd for assistance.

Test setup
- Ensure that the lot number of the cartridge matches that of the sample buffer, and the ID Chip.
- If the sealed cartridge and sample buffer have been stored in refrigerator, place them at room temperature (18-25 ℃) at least 30 minutes before measurement.
- Turn on the instrument for infinosis™ tests.
  Refer to the *'instrument for infinosis™ tests Operation Manual'* for the complete information and operating instructions.

Test procedure
1. Insert ID Chip into the instrument for infinosis™ tests and read ID chip information.
2. Using a pipette to transfer **20 µL** of sample (Human whole blood/plasma/serum) to the **sample buffer tube** provided in the kit.
3. Close the lid of the sample mixing tube and mix the sample thoroughly for **5-10 seconds** by tapping or inverting the tube.
4. Pipette out **100 µL** of **sample mixture** and load it onto the sample well on the cartridge.
5. Leave the sample-loaded cartridge at room temperature for **15 minutes.**
6. Insert the sample-loaded cartridge into the cartridge holder of instrument for infinosis™ tests.
   Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder.
7. Press **"Test"** button on the instrument for infinosis™ tests.
8. Instrument for infinosis™ tests will start scanning the sample-loaded cartridge immediately.
9. Read the test result on the display screen of the instrument for infinosis™ tests.
10. Print out the testing results when press **"Print"** button on the instrument for infinosis™ tests.

Limitations - interference

IVD CE

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- This test has been developed for testing human whole blood, serum, plasma specimen only.
- The results of Infinosis™ myoglobin should be evaluated with all clinical and laboratory data available. If myoglobin test results do not agree with the clinical evaluation, additional tests should be performed.
- The false positive results may come from cross-reactions with some similar antibodies in blood, and similar epitopes from non-specific components in blood capturing fluorescent labeled antibodies.
- The false negative results may from some unknown substance blocking epitope adhering antibodies, unstable or degenerated myoglobin that cannot be identified due to prolonged time and temperature and storage condition of sample and reagent.
- Other factors may interfere with Infinosis™ myoglobin and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Measuring range
5.0- 400 ng/mL (defined by the lower detection limit and the maximum of the master curve). Values below the lower detection limit are reported as < 5.0 ng/mL. Values above the measuring range are reported as > 400 ng/mL.

Lower detection limit
5.0 ng/mL
The detection limit represents the lowest analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (master calibrator, standard 1+2 SD, repeatability study, n = 21).

Expected values
0- 60 ng/mL
Expected values may vary with age, sex, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practice.

Specific performance data
Representative performance data are given below. Results obtained in individual laboratories may differ.

Precision
Intra-assay
Determined by by using 10 replicates of specimen of 120 ng/mL Myoglobin
CV ≤ 15%

Inter-assay
Determined by using 3 replicates for each of three lots using Myoglobin specimen levels at 120 ng/mL, CV ≤ 15%.

Linearity
A serial concentration of Myoglobin controls at 15 ng/mL, 40 ng/mL, 60 ng/mL, 100 ng/mL, 250 ng/mL, 350 ng/mL were each tested for three times, the Correlation Coefficient is: r ≥ 0.9962

Method comparison
A comparison of the Infinosis™ Myoglobin assay (y) with the Roche Myoglobin STAT assay (x) using 178 clinical samples gave the correlation: r=0.9653

Functional sensitivity
5.12 ng/mL
The functional sensitivity is the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of ≤ 20 %

References

1. Universal protein resource accession number P02144 at UniProt.
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3. Naka T, Jones D, Baldwin I, Fealy N, Bates S, Goehl H, Morgera S, Neumayer HH, Bellomo R (Apr 2005). "Myoglobin clearance by super high-flux hemofiltration in a case of severe rhabdomyolysis: a case report". Critical Care. 9 (2): R90-5. doi:10.1186/cc3034. PMC 1175920. PMID 15774055.
4. Weber M, Rau M, Madlener K, Elsaesser A, Bankovic D, Mitrovic V, Hamm C (Nov 2005). "Diagnostic utility of new immunoassays for the cardiac markers cTnI, myoglobin and CK-MB mass". Clinical Biochemistry. 38 (11): 1027–30. doi:10.1016/j.clinbiochem.2005.07.011. PMID 16125162.
5. Dasgupta A, Wahed A (2014). "Cardiac Markers". Clinical Chemistry, Immunology and Laboratory Quality Control. Elsevier. pp. 127–144. doi:10.1016/b978-0-12-407821-5.00008-5. ISBN 978-0-12-407821-5.

Symbols

IVD In vitro diagnostic medical device	 Temperature limit	 Consult instructions for use	REF Catalog number
LOT Batch code	 Date of manufacture	 Use-by date	 Contains sufficient for <n> tests
 Manufacturer	 Do not re-use	 Do not use if package is damaged and consult instructions for use	
CE European Conformity	EC REP Authorized representative in the European Community		

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