Instruction For Use

【Product Name】

Myoglobin STAT (MYO STAT) eCLIA

【Order Information】

REF NO.	Package Size
691035	50T
691036	2×50T
691037	100T
691038	2×100T

【Intended Use】

Myoglobin STAT (MYO STAT) eCLIA is an immunoassay reagent for in vitro quantitative determination of myoglobin (MYO) in human serum and plasma by fully automated immunassay analyzer to aid diagnosis of acute myocardial infarction.

Myoglobin (MYO) is a single peptide chain composed of 153 amino acid residues located in the cytoplasm of both cardiac and skeletal muscle cells[1]. The molecular weight of myoglobin is 17.8 KD that is hence small enough to pass rapidly into the circulation following damage to cardiac and skeletal muscle cells. Myoglobin can avoid being filtered by glomerulus[2,3]. The serum or plasma myoglobin level will start to increase between 1-2 hours after AMI (Acute Myocardial Infarction) has occurred, peaking at 6-9 hours. The myoglobin level of almost all the AMI patients will increase within 12 hours and fall back to baseline after 24 hours and rise rapidly when AMI has occurred again, forming a "multi peak" phenomenon which can reflect the periodic spontaneous reinfarction and reperfusion of the coronary arteries in the ischemic cardiac muscle cells. So myoglobin is regarded as a very early maker of acute AMI[4].The myoglobin will rise by acute muscle injury, acute and chronic kidney failure, severe congestive heart failure, long shock, neuromuscular disease (Muscular Dystrophy, Myoatrophy, polymyositis), myopathy caused by various reasons, intramuscular injection, strenuous exercise, some kind of toxin and drug. The myoglobin level of patients undergoing cardiac surgery can be regarded as an objective indicator for judging the degree of damaging or healing of cardiac muscle cell.

【Test Principle】

Sandwich principle. Total duration of assay: 9 minutes.

5 μL of sample, biotin-labeled MYO monoclonal antibody and the ruthenium (Ru) complex-labeled MYO monoclonal antibody form an antigen-antibody sandwich complex, which is bound to streptavidin coated magnetic particles, and then transferred to the measuring cell where the magnetic particles are captured onto the surface of the electrode, and streptavidin coated magnetic particles, while the unbound substances are washed away. Chemiluminescence is generated after the electrode is electrified, and the generated optical signal is measured by a photomultiplier, processed by an instrument, and the concentration of MYO in the sample is calculated based on the calibration curve.

【Main Components】

The reagent pack consists of MB, RA, RB, calibrators. Different lots cannot be used at the same time or mixed up together.

Components	Ingredients	Volume (50T)	Volume (2×50T)	Volume (100T)	Volume (2×100T
(MB)	Streptavidin-coated micro magnetic beads, 0.75mg/mL; 0.1M PBS; 0.05 % ProClin™ 300	1×1.8 mL	2×1.8 mL	1×3.5 mL	2×3.5 mL
(RB)	Anti-MYO-Ab~biotin, 1.75mg/L; 0.1M PBS; 0.05 % ProClin™ 300	1×3.8 mL	2×3.8 mL	1×7.5 mL	2×7.5 mL
(RA)	Anti-MYO-Ab~Ru(bpy)$_3^{2+}$,1.75mg/L; 0.1M PBS; 0.05 % ProClin™ 300	1×3.8 mL	2×3.8 mL	1×7.5 mL	2×7.5 mL
Calibrators	Bovine serum; MYO antigen; 0.05 % ProClin™ 300; lyophilized	High: 1×1.0 mL Low: 1×1.0 mL			

Traceability: This method can be traced back to the Roche Elecsys MYO.

Supporting instruments and materials required but not provided in this pack (provided by Lifotronic)

Additional materials for Automated ECL Immunoassay Analyzer eCL8000, eCL8000i, eCL8000p, eCL8000x:

- REF 679005, Auffer, 480 mL, or REF 679004, Auffer, 6×480 mL
- REF 679007, Buffer, 480 mL, or REF 679006, Buffer, 6×480 mL
- REF 679009, Concentrated Washing Buffer, 1 L, or REF 679008, Concentrated Washing Buffer, 6×1 L
- REF 691027, Multi Control Cardiac Marker, Low value: 3 × 2.0 mL, High value: 3× 2.0 mL, or REF 691028, Multi Control Cardiac Marker, Low value: 6 × 2.0 mL, High value: 6 × 2.0 mL
- REF 679011, Assay Cup, 300 T, or REF 679012, Assay Cup, 3000 T

Additional materials for Automated ECL Immunoassay Analyzer eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p:

- REF 0320501804, Auffer, 2×1 L, or REF 0320501805, Auffer, 4×1 L
- REF 0320501904, Buffer, 2×1 L, or REF 0320501905, Buffer, 4×1 L
- REF 0320507502, PreClean, 2×800 mL, or REF 0320507503, PreClean, 4×800 mL
- REF 691027, Multi Control Cardiac Marker, Low value: 3 × 2.0 mL, High value: 3× 2.0 mL, or REF 691028, Multi Control Cardiac Marker, Low value: 6 × 2.0 mL, High value: 6 × 2.0 mL
- REF 0320510001, Assay Cup/Assay Tip, 6×6×105, or REF 032120111, Assay Cup/Assay Tip, 12×2×105

Additional materials for Automated ECL Immunoassay Analyzer eCL9000, eCL9600, eCL9900, eCL9900i:

- REF 0320501801, Auffer, 2×2 L, or REF 0320501806, Auffer, 4×2 L
- REF 0320501901, Buffer, 2×2 L, or REF 0320501906, Buffer, 4×2 L
- REF 0320507501, PreClean, 2×2 L, or REF 0320507504, PreClean, 4×2 L
- REF 691027, Multi Control Cardiac Marker, Low value: 3 × 2.0 mL, High value: 3× 2.0 mL, or REF 691028, Multi Control Cardiac Marker, Low value: 6 × 2.0 mL, High value: 6 × 2.0 mL
- REF 0320510001, Assay Cup/Assay Tip, 6×6×105, or REF 0320510002, Assay Cup/Assay Tip, 1×6×10

【Storage and Shelf Life】

Store at 2°C-8°C.

Do not freeze.

Store the reagent kit upright in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Damaged, expired or contaminated reagents should be discarded.

Stability of the reagents	
Unopened at 2°C~8°C	18 months
Store at 2°C~8°C after opening	8 weeks
Stored on the analyzers at 2°C~15°C	8 weeks

The calibrators are stable up to the stated expiration date.

Stability of the calibrators	
Unopened store at 2°C~8°C	18 months
Store at 2°C~8°C after reconstituted	7 days
Store at -25°C~-15°C after reconstituted	3 months (freeze only once)

【Applicable Instrument】

Automated ECL Immunoassay Analyzers: eCL8000, eCL8000i, eCL8000p, eCL8000x, eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p, eCL9000, eCL9600, eCL9900, eCL9900i.

【Specimen collection, handling and storage】

Human serum and plasma added with heparin lithium, heparin sodium and EDTA-2K、EDTA-3K anti-coagulants are recommended.

Blood samples should be collected by standard operation of venous puncture; after complete coagulation, the tangible component should be removed by centrifugation. The sample should avoid bubbling during testing. Lipid layer floating on the upper of the sample should be removed. Samples with severe hemolysis are not recommended.

Samples would better to be tested in 16 hours after collection at room temperature (18~28°C), otherwise, should be stored at 2~8°C for no more than 7 days or at -25~-15°C for 90 days. Freezing and thawing cycle is permitted only once.

【Assay Procedure】

Testing procedures and precautions

Previous to operation, users should read the operational manual carefully to obtain system operation procedure, sample processing, security precaution, maintenance and other related information.

Set up Myoglobin STAT (MYO STAT) test according to the operational manual.

Put the MYO STAT rackpack into the correct analyzer slot to automatically suspend magnetic beads at least 30 min before testing.

Recommended test temperature: 10~30°C; Relative humidity: ≤ 80%.

Handing of lyophilized calibrators and control materials

Carefully dissolve the contents of calibrator by adding exactly 1.0 mL of distilled or deionized water and allow to stand closed at room temperature for at least 20 minutes to reconstitute. Mix carefully, avoiding foam formation. Transfer aliquots of the reconstituted calibrators to the additional plastic bottles. After bottles is marked and dispensed. If you do not test immediately, you need to store the aliquots immediately at -15°C or lower than -15°C.

Calibration

Calibration should be performed using lot-matching reagent and calibrators.

Before calibration, the reagent and main curve information should be imported into the analyzer via radio frequency identification (RFID) reagent card (refer to instrument user manual). The analyzer adjusts the main curve to produce working curve according to the calibrator results, and identifies validity of the working curve automatically.

Recalibration is recommended when:

(1) The reagents of different lot are used;

(2) Tthe same lot of reagents were used on the analyzer beyond 28 days;

(3) Quality control misses the target.

(4)The Buffer of different lots are used.

Quality control

For quality control, use Multi Control Cardiac Marker.

In addition, other suitable control material can be used.

Control materials for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

If necessary, repeat the measurement of the samples concerned.

Follow the applicable government regulations and local guidelines for quality control.

Please make sure that the correct values are used.

Calculation

The system software automatically calculates the analyte concentration using particular algorithm, and the result unit is ng/mL or μg/L : 1 ng/mL=1 μg/L

Specimen dilution

Samples exceeding the measuring range would be manually diluted with myoglobin-negative serum.

The recommended dilution ratio is 1:10 and the diluted sample test results need to multiply dilution ratio.

【Biological reference interval】

According to serum test results of 860 healthy human (males 465, females 395) , The results as follows:

The crowd	Numbers	95th percentile (ng/mL)
Male	465	72
Female	395	58

Due to differences in the region, race, gender and age, laboratories are recommended to set up their own reference ranges.

【Result Interpretation】

For explaining the result, the patient's overall clinical manifestation should be referred to, including symptoms, medical history and other relevant data and information.

【Limitations】

Test results are used only for clinical reference and cannot be used as the basis for diagnosis or rule-out of diseases alone.

The measuring range of the kit is 21~3000 ng/mL. For samples with MYO content below the lower detection limit, the results are reported in < 21 ng/mL. If the MYO content is above the upper detection limit, then the sample should be diluted and re-tested. The results are reported after multiplying with the dilution factor. The recommended dilution ratio is 1:10 and the diluted sample test results need to multiply dilution ratio.

Even the concentration of MYO reached 10000 ng/mL, hook effect is unobservable.

When the sample containing triglyceride ≤ 2200 mg/dL, bilirubin ≤ 65 mg/dL, hemoglobin ≤ 1.4 g/dL, total protein ≤ 10 g/dL, biotin ≤ 50 ng/mL, HAMA (human anti-murine antibodies) ≤ 200 ng/mL interference deviation to the test result lies within ±10%. The relative recovery rate is between 90% and 110% when the rheumatoid factor concentration ≤ 1500 IU/mL.

【Analytical Performance】

Lower limit of measurement

Limit of Detection = 21 ng/mL.

Accuracy

The recovery of samples added myoglobin with different concentrations should fall between 85% and 115%.

Linearity

The correlation coefficient (Pearson's r) is not less than 0.9900 in the interval of 21~3000 ng/mL.

Within-run precision (repeatability)

The coefficient of variation (CV) ≤ 7.5%.

Between-lot precision

The coefficient of variation (CV) ≤ 10%.

Analytical specificity

Test result of blank samples spiked with analogs below is lower than 21 ng/mL.

Analog	Concentration (g/dL)
Hemoglobin	1.4

Homogeneity of calibrators and control materials

Within-bottle homogeneity: coefficient of variation (CV) ≤ 7.5%.

Between-bottle homogeneity: coefficient of variation (CV) ≤ 10%.

Method comparison

A comparison of the Lifotronic MYO STAT assay (y) with the Roche Elecsys Myoglobin STAT Method (x) using clinical samples gave the following correlations:

Number of samples measured: 121

Linear regression:

y=-1.289+0.993x

r = 0.995

The sample concentrations were between approx 21 and 3000 ng/mL.

【Precaution and Warning】

The kit is only used for in vitro diagnostics.

When using the kit, it's necessary to comply with regulations in the laboratory.

All reagents and samples including specimen, calibrators and control materials, should avoid foaming before and during test.

Test results of the kit are for clinical reference only, and clinical evaluation of patients should be combined with their symptoms and signs, medical history, other laboratory examination results and treatment responses.

Due to factors such as methodology or antibody specificity, testing identical samples with reagents from different manufacturers may get different results, and the results from different kits should not compare directly, lest cause the wrong medical explanation. It's suggested that laboratorians should point out the characteristics of used reagent in the test report to the clinician. In serial monitoring, if the reagent type is changed, a continuous parallel test should be performed and comparison of the results to the former to determine new baseline value.

This product contains animal-sourced materials and may have potential biological risk. All samples and test wastes should be treated as the source of infection, and all wastes must be disposed according to local regulations.

The preservative ProClin™300 which contain Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1): May cause an allergic skin reaction. thus, proper personal protection should be adopt while handling the reagent: avoid breathing dust/fume/gas/mist/vapours/spray, wear protective gloves and contaminated work clothing should not be allowed out of the workplace. If skin irritation or rash occurs: get medical advice/attention, take off contaminated clothing and wash it before reuse, and dispose of contents/container to an approved waste disposal plant

【Reference】

1. Lee HS, Cross SJ, Garthwaite P, et al. Comparison of the value of novel rapid measurement of myoglobin, creatine kinase, and creatine kinase MB with the electrocardiogram for the diagnosis of acute myocardial infarction. Br Heart J 1994; 71(4): 311-315.
2. Bakker AJ, Koelemay MJ, Gorgels JP, et al. Troponin T and myoglobin at admission: value of early diagnosis of acute myocardial infarction. Eur Heart J 1994; 15(1): 45-53.
3. Katus HA, Diederich KW, Scheffold T, et al. Non-invasive assessment of infarct reperfusion: the predictive power of the time to peak value of myoglobin, CKMB, and CK in serum. Eur Heart J 1988; 9(6): 619-624.
4. Lavin F, Kane M, Forde A, et al. Comparison of five cardiac markers in the detection of reperfusion after thrombolysis in acute myocardial infarction. Br Heart J 1995; 73(5): 42.

【Symbols Explanation】

Symbol	Title of Symbol	Symbol	Title of Symbol
	Manufacturer		Consult instructions for use
	Use-by date	IVD	In vitro diagnostic medical device
LOT	Batch code	Σ	Sufficient for <n> tests
SN	Serial number		Biological risks
	Temperature limit		This way up
EC REP	Authorized representative in the European Community	CE	Indicates this device is in compliance with Europe Directive.
REF	Catalogue number	P/N	Material code
	Warning		Date of manufacture
UDI	Unique device identifier		

【Manufacturer】

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【Version and Revision】

Version: 2.0

Issue Date:2025-03-04