Instruction For Use

【Product Name】

MPO (eCLIA)

【Order Information】

REF NO.	Package Size
0320509201	50 T
0320509202	2×50 T
0320509203	100 T
0320509204	2×100 T

【Intended Use】

MPO (eCLIA) is an immunoassay reagent for in vitro quantitative determination of myeloperoxidase (MPO) activity in human serum or plasma.

【Summary】

MPO is a heme protease with a heme auxiliary group stored in white blood cells. It is a member of the heme peroxidase superfamily and can catalyze the reaction of hydrogen peroxide (H_2O_2) and chloride ions (Cl^-) to produce hypochlorous acid, thereby promoting oxidative damage in the inflammatory site of arteries[1]. MPO has been shown to accumulate in atherosclerotic plaques in clinical studies, and MPO concentrations can be used for risk grading in patients with acute coronary syndrome (ACS)[2]. Patients with chest pain who have elevated MPO are at risk for early myocardial infarction (MI)[3]. Meanwhile, elevated MPO concentrations have been shown to be associated with chronic heart failure, and MPO can also be used clinically to grade patients with heart failure (HF)[4], as a cardiovascular risk predictor independent of other myocardial markers[5]. Clinically, it is mainly used for the auxiliary diagnosis of cardiovascular system inflammation

【Test Principle】

Sandwich principle. Total duration of assay: 9 minutes.

20 μL of sample, biotinylated MPO monoclonal antibody and MPO monoclonal antibody labeled with ruthenium complex form a sandwich complex. After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with system reagent. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. Results are determined via a calibration curve which is instrument specifically generated by 2-point calibration and a master curve provided via the RFID.

【Main Components】

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

Components	Ingredients	Volume (2×50T)	Volume (50T)	Volume (100T)	Volume (2×100T)
(MB)	Streptavidin-coated microparticles 0.45mg/mL; ProClin300	2×1.8mL	1×1.8mL	1×3.5mL	2×3.5mL
(RB)	biotinylated MPO monoclonal antibody 1.0mg/L; PBS; ProClin300	2×3.5mL	1×3.5mL	1×7.0mL	2×7.0mL
(RA)	MPO monoclonal antibody labeled with ruthenium 1.0mg/L; PBS; ProClin300	2×3.5mL	1×3.5mL	1×7.0mL	2×7.0mL
Calibrators	MPO antigen, lyophilized	High: 1×1.0 mL Low: 1×1.0 mL			
Control Materials (Optional)	MPO antigen, lyophilized	High: 1×2.0 mL Low: 1×2.0 mL			

Traceability: This method can be traced to manufacturer's selected measurement procedures.

See the control material value sheet for the target values and ranges of control materials.

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 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 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 0320507501, PreClean, 2×2 L, or REF 0320507504, PreClean, 4×2 L
- REF 0320510001, Assay Cup/Assay Tip, 6×6×105, or REF 0320510002, Assay Cup/Assay Tip, 1×6×105.

【Storage and Shelf Life】

Store at 2℃-8℃.

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 store at 2℃~8℃	18 months
Store at 2℃~8℃ after opening	8 weeks
Stored on the analyzers at 2℃~15℃	8 weeks

The calibrators and control materials are stable up to the stated expiration date.

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

Store calibrators and control materials upright in order to prevent the calibrators and control materials from adhering to the cap of the vial.

【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 anticoagulant plasma with lithium heparin, heparin sodium, EDTA-K2, and EDTA-K3 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 in suggestion. Samples should be stable for 8 hours at 18~28℃, 2 days at 2~8 ℃ or 3 months at -15℃ or lower than -15℃.

Samples should avoid repeated freeze-thaw cycles. Do not use the samples after five freeze-thaw cycles.

Refrigerated/frozen samples must be restored to room temperature before testing.

【Assay Procedure】

Testing procedures and precautions

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

Set up MPO test according to the operational manual.

Put the MPO reagent pack into the correct analyzer slot to automatically suspend magnetic beads at least 30 min before testing.

Recommended ambient 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 15 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℃ or lower than -15℃.

Carefully dissolve the contents of control materials by adding exactly 2.0 mL of distilled or deionized water and allow to stand closed at room temperature for at least 15 minutes to reconstitute. Mix carefully, avoiding foam formation. Transfer aliquots of the reconstituted control materials 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℃ or lower than -15℃.

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 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) The same lot of reagents were used on the analyzer beyond 28 days;

(3) Quality control findings outside the defined limits;

(4) Change buffer with different batch numbers.

Quality control

For quality control, use MPO Control Materials.

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 pmol/L.
Conversion factor: pmol/L × 0.145 = ng/mL.

Specimen dilution
MPO concentration in the sample higher than the upper limit of detection can be diluted with sample diluent.
The recommended dilution ratio is 1:5 (automatic dilution by instrument or manual dilution). If manual dilution, the result should be multiplied by the dilution ratio. If instrument automatic dilution, the instrument will automatically calculate the result.

【Biological Reference Interval】
By analyzing 260 serum samples of healthy people, it was calculated that the upper limit of the reference range of 95% is 93.32 ng/mL.
Due to the differences in geography, race, gender and age, it is recommended that each laboratory determine the applicability of reference range through tests, and establish the reference range of this laboratory if necessary.

【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】
The test results are only for clinical reference and cannot be used alone as the basis for diagnosis or exclusion of cases.
The measuring range of the kit is 0.5~1400 ng/mL. For samples with MPO content below the lower detection limit, the results are reported as < 0.5 ng/mL; If the MPO content is above the upper detection limit, the results are reported as > 1400 ng/mL (5× diluted sample is reported as > 7000 ng/mL).
When jaundice (bilirubin) ≤ 20 mg/dL, hemolysis (hemoglobin) ≤ 1000 mg/dL, lipemia (triglyceride) ≤ 2000 mg/dL, biotin ≤ 20 ng/mL, and HAMA ≤ 100 ng/mL in the sample, the interference deviation of the measured results is within ±10%.
When the concentration of rheumatoid factor in the sample ≤ 1200 IU/mL, the relative recovery of the test results is between 90% and 110%.
When the MPO concentration reaches 20000 ng/mL, the test results are not be affected by the hook effect.

【Analytical Performance】
Lower limits of measurement
Limit of Blank = 0.5 ng/mL
Limit of Detection = 2 ng/mL.
Accuracy
The relative deviation shall not exceed ±10%.
Linearity
The correlation coefficient is not less than 0.9900 in the interval of 2~1400 ng/mL.
Within-run precision (repeatability)
The coefficient of variation (CV) ≤ 8%.
Between-lot precision
The coefficient of variation (CV) ≤ 10%.
Homogeneity of calibrators and control materials
Between-bottle homogeneity: The coefficient of variation (CV)≤ 10%.
Accuracy of calibrators
The supporting calibrators of the kit are tested, the relative deviation of test results is within ±10%.
Measured values of control materials
The measured results of supporting assigned quality control of the kit should be within the quality control range.
Method comparison
A comparison of the Lifotronic MPO assay (y) with the commercial MPO reagent kit (x) using clinical samples gave the following correlations:
Number of serum samples measured: 108
Linear regression:
y=1.0093X-4.7211
r = 0.987
The sample concentrations were between 2.906 and 1262 pg/mL.

【Precaution and Warning】
The kit is only used for in vitro diagnostics.
Exercise the normal precautions required for handling all laboratory reagents.
All reagents and samples including specimen, reagents and calibrators should avoid foaming before and during test.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.
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.
Any serious incident that would be occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
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.

【Literature References】
1. Bogdan Ioan Coculescu, et al. Myeloperoxidase, a possible biomarker for the early diagnosis of cardiac diastolic dysfunction with preserved ejection fraction. JOURNAL OF ENZYME INHIBITION AND MEDICINAL CHEMISTRY. 2018;33(1): 1292-98.
2. Mihir D. Mehta, et al. A Synergistic Role of Myeloperoxidase and High Sensitivity Troponin T in the Early Diagnosis of Acute Coronary Syndrome. Ind J Clin Biochem. 2016;31(1): 75-80.
3. Meuwes, et al. Serum Myeloperoxidase Levels Are Associated With the Future Risk of Coronary Artery Disease in Apparently Healthy Individuals: The EPIC-Norfolk Prospective Population Study. JACC. 2007;50(2): 159-65.
4. Stephen J. Nicholls, et al. Risk Prediction with Serial Myeloperoxidase Monitoring in Patients with Acute Chest Pain. Clinical Chemistry. 2011; 57(12):1762-70.
5. William M. Nauseef, M.D. Biosynthesis of Human Myeloperoxidase. Arch Biochem Biophys. 2018 March 15, 642: 1-9.

【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		

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【Version and Revision】
Version: 2.0
Issue Date: 2025-03-05