Instruction for Use

【Product Name】

Multi Control Cardiac Marker

【Package】

REF NO.	Package Size
691027	Low value: 3 × 2.0 mL, High value: 3× 2.0 mL
691028	Low value: 6 ×2.0 mL, High value: 6 × 2.0 mL

【Intended Use】

Multi Control Cardiac Marker is an immunoassay quality control serum for in vitro quantitative determination of Troponin I (cTnI), Myoglobin (MYO), Creatine Kinase MB (CK-MB), N-terminal pro B-type Natriuretic Peptide (NT-proBNP) and MYO STAT, CK-MB STAT, NT-proBNP STAT in lifotronic calibrators and its supporting reagents by fully automated immunassay analyzer to control the quality of the corresponding calibration items during detection.

【Test Principle】

This product is a compound quality control material. The quality control product is measured by the corresponding test procedure. The results are compared with target range to determine whether the assay run is in control.

【Main Component】

The kit is freeze-dried equine serum products containing native troponin (cTnI), recombinant myoglobin, native creatine kinase MB (CK-MB), recombinant N-terminal pro B-type natriuretic peptide (NT-proBNP).

See the Multi Control Cardiac Marker value sheet for the target values and ranges of Multi Control Cardiac Marker.

【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 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 0320510001, Assay Cup/Assay Tip, 6×6×105, o REF 0320510002, Assay Cup/Assay Tip, 1×6×105

【Applicable Instrument】

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

【Storage and Shelf Life】

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

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

【Assay Procedure】

Testing procedures and precautions

Before the test, we should carefully read the system operation manual of the analytical instrument to obtain the relevant information of the system operating rules, sample management, safety precautions, maintenance and maintenance, and prepare the required materials for testing. Invoke and set up the project determination procedure according to the system operation rules.

Handing of lyophilized control materials

Carefully dissolve the contents of one bottle by adding exactly 2.0 mL of distilled or deionized water and allow to stand closed for 10~15 minutes to reconstitute. Mix carefully, avoiding foam formation. Transfer aliquots of the reconstituted calibrators or control materials to the additional bottles, after bottles is marked and dispensed. If you do not test immediately, you need to store the aliquots immediately at -25~-15°C.

Quality control

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.

【Result Interpretation】

The measuring results must be within the target range encoded in the lot-matching quality control card. Laboratories are recommended to establish their own target values and ranges according to local quality control rules.

【Limitations】

If there are signs of microbial contamination or significant turbidity, the reagent should be abandoned.

【Assay Performance】

Homogeneity

Within-bottle homogeneity: CV ≤ 7.5%

Between-bottle homogeneity: CV ≤ 6.0%

【Precaution and Warning】

This product is only use for in vitro diagnostics.

The target values and ranges and batch numbers of the product should be corresponded before use;

Disposal of all waste material should be in accordance with local guidelines.

Safety data sheet available for professional user on request.

This product contains human- and 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.

【Symbol 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
	Temperature limit		Biological risks
EC REP	Authorized representative in the European Community		This way up
REF	Catalogue number	CE	Indicates this device is in compliance with Europe Directive.
	Warning	P/N	Material code
UDI	Unique device identifier		Date of manufacture

【Manufacturer】

Shenzhen Lifotronic Technology Co., Ltd.

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【Version and Revision】

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