

Instructions for Use Cardiopulmonary Markers Controls

[Product Name]

Cardiopulmonary Markers Controls

[Packing Size]

L: 3×3.0 mL

H: 3×3.0 mL

[Intended Use]

This product is intended to be used in combination with reagent and calibrators for internal quality control of the assay system. It checks system status during in vitro quantitative determination of TnI, CK-MB, MYO, NT-proBNP, D-Dimer in human serum, plasma, and whole blood sample.

[Principle]

Test procedure of controls is the same as the test procedure of samples. Control test results are analyzed or compared to specific target values to judge whether the test system meets specific requirements.

[Main Components]

Component	Ingredients	Fill Volume
Cardiopulmonary markers controls L	Low-concentration TnI (human); CK-MB (human); MYO (human); NT-proBNP (recombinant); D-Dimer (human); Tris buffer solution, 25 mM; ProClin 300, 1 g/L	3×3.0 mL
Cardiopulmonary markers controls H	High-concentration TnI (human); CK-MB (human); MYO (human); NT-proBNP (recombinant); D-Dimer (human); Tris buffer solution, 25 mM; ProClin 300, 1 g/L	3×3.0 mL
Reconstitution solvent	Purified water	6×3.0 mL

Note: Components in different lots of reagent cannot be mixed or exchanged for use.

Each batch of control has its specificity. For details about the target value and its acceptable range, see the target value form.

Instrument or material required but not provided (by Medcaptain):

- (1) SMART 6500 Automated Chemiluminescence Immunoassay Analyzer, SMART 500S Automated Chemiluminescence Immunoassay Analyzer, Immu F6 Automated Chemiluminescence Immunoassay Analyzer, and Immu F6S Automated Chemiluminescence Immunoassay Analyzer;
- (2) Reaction cups;
- (3) 500µL pipette tips;
- (4) Washing buffer;
- (5) Trigger solution;
- (6) Pre-trigger solution;
- (7) TnI (CLIA) Reagent Kit;
- (8) CK-MB (CLIA) Reagent Kit;
- (9) MYO (CLIA) Reagent Kit;
- (10) NT-proBNP (CLIA) Reagent Kit;
- (11) D-Dimer (CLIA) Reagent Kit;
- (12) hs-TnI (CLIA) Reagent Kit.

[Storage Condition and Shelf Life]

Storage condition: Sealed and stored at 2~8°C. Do not freeze.

Shelf life: 14 months

After being reconstituted, the shelf life of controls is 1 day at room temperature (10~30°C), 3 days at 2~8°C, and 60 days at -20°C. The control is allowed to be frozen and thawed only one cycle.

Manufacturing and expiration dates can be found on labels and package.

[Applicable Instrument]

Chongqing Keysmile SMART 6500 Automated Chemiluminescence Immunoassay Analyzer

Chongqing Keysmile SMART 500S Automated Chemiluminescence Immunoassay Analyzer

Medcaptain Immu F6 Automated Chemiluminescence Immunoassay Analyzer

Medcaptain Immu F6S Automated Chemiluminescence Immunoassay Analyzer

[Test Procedure]

- Reconstitute the controls according to the following steps:
- Pour a vial of solvent (3.0mL/bottle) into the control bottle, re-cap the vial and reconstitute the control, wait about 10min for reconstitution, and gently shake the bottle several times until the control is totally reconstituted. Avoid air bubbles during the reconstitution process. After being reconstituted, the control can be split into aliquots, marked, and stored under proper conditions for future use. The subdivided control can be used for only one time.
- Select control-related settings, enter the control information, and request control tests according to the operation manual of test system.
- Two levels of Cardiopulmonary markers controls should be tested in accordance with any local applicable regulations, to ensure reliability of the test system. It is highly recommended to always run control tests every time reagent lot has been changed, performing a calibrator test, conducting troubleshooting, or after maintenance service.
- Each laboratory is recommended to establish its own control values and allowed ranges, based on its own conditions.

[Interpretation of Results]

The control test result must fall within the target value range. Otherwise, check the test system to identify root cause of the problem. For example, check the expiration date and storage condition of the controls, and check the status of instrument and performance. After eliminating the problem, test the control again. If test result still exceeds the limit, contact after-sale service department of Medcaptain.

[Limitation]

The control is impacted by limitation of the test system. Deviation of results indicates that one or multiple components of the test system are abnormal.

[Product Characteristics]

1. Appearance

- (1) The package of controls should be intact without any damage, with all components in the package. The appearance is clean and tidy, the

label is clear, and no liquid leakage can be found.

(2) The control should be white or faint yellow freeze-dried powder with no dent or trace of liquid. After being reconstituted, the control should be homogeneous liquid without any visible particles or sediments.

(3) The reconstitution solvent should be clear and transparent liquid without any sediments, insoluble particles, or floccules.

2. Fill Volume

The fill volume of reconstitution solvent must be in the range of (2.7~3.3mL).

3. Accuracy

After analyzer calibration using matched set of calibrators, perform control tests. The results must fall within the target ranges.

4. Homogeneity

4.1. Within-bottle Homogeneity

The within-bottle homogeneity of the control must meet the following requirement: CV≤8.0%.














4.2 Between-bottle Homogeneity

The between-bottle homogeneity of the control must meet the following requirement: CV≤5.0%.

[Precautions]

- 1 This product is for IVD use only.
- 2 This product is intended to be used by professionals only.
- 3 Do not use the product if it is expired.
- 4 The control must be sealed and placed at 2~8°C for storage.
- 5 During use of this product, operate by strictly following the operation procedures as written in Instructions for use and following guidelines in each laboratory.
- 6 Lab operator must wear protective gloves when using the product. In case of accidental exposure to the reagent, flush the body part with a large volume of water immediately. If reagent splashes into eyes, flush eyes with copious of water and consult a doctor immediately.
- 7 All samples and reaction wastes must be treated as potentially biohazard¹, and all wastes must be disposed of according to local laws and regulations².


[Symbol Description]

	Temperature limit		Date of manufacture
	<i>In vitro</i> diagnostic medical device		Catalog number
	Lot Number		Consult instructions for use
	Use-by date		Authorized representative in the European Community
	This way up		CE Marking
	Manufacturer		Unique device identifier
	Biological risks		

[References]

- [1] US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington, DC: US Government Printing Office; December 2009.
- [2] World Health Organization. Laboratory Biosafety Manual. 3rd ed. Geneva: World Health Organization; 2004.

[Basic Information]


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[Issued on]
Aug., 11, 2023