Finecare™

cTnI/CK-MB/Myo Multi-Control

Catalog No. W817

Level 1: 1×0.5 mL, Level 2: 1×0.5 mL, Level 3: 1×0.5 mL

INTENDED USE

The Finecare™ cTnI/CK-MB/Myo Multi-Control is intended for use as quality control by monitoring precision of Finecare™ cTnI/CK-MB/Myo Rapid Quantitative Test.

For in vitro diagnostic use only.
For professional use.

SUMMARY AND PRINCIPLE

The cTnI/CK-MB/Myo antigen contained in the control react with specific antibodies in the test strip, which is based on fluorescence immunoassay technology using a sandwich immunodetection method.
Finecare™ FIA Meters shows cTnI/CK-MB/Myo concentrations in the control.

PRECAUTIONS

1. This product is for in vitro diagnostic use only. Do not swallow.
2. Do not mix components from different control lots. This instruction for use applies to this lot of product only.
3. Do not use product beyond the expiration date printed on the package.
4. Tests should be applied by well-trained healthcare professionals, and conducted in central laboratories.
5. Do not use the control if the vial is damaged or not well sealed.
6. Do not use the control if there is agglomeration or floccule after dissolved. Discard it and use another new control.
7. Operate in accordance with the instructions, strictly control the room temperature, sample addition and testing time.
8. If an expected value is not obtained, please check whether the test kit is expired or the operation is improper. If not, please use another new control to retest.
9. The used control and used materials, such as test cartridges, are biomedical waste. Proper safety techniques, handling and disposal methods should be followed in accordance with standard procedures and relevant regulations observed for microbiological hazard materials.
10. If you have any questions or need help, please contact the local distributor to solve problems timely.
11. Notice to the users: Any serious incident that has occurred in relation to the Finecare™ cTnI/CK-MB/Myo Multi-Control shall be reported to the manufacturer and the competent authorityin which the user and/or the patient is established.
12. The human source material used to manufacture this control was tested and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2. This product may also contain other human source materials for which there are no approved tests. All human source material should be considered potentially infectious and handled with the same precautions used with patient specimens. Proper laboratory safety techniques, handling and disposal methods should be followed in accordance with standard procedures and relevant regulations observed for microbiological hazard materials.

MATERIAL

The control mainly contains cTnI antigen, human CK-MB antigen, human Myoglobin antigen, 0.01mol/L Tris-HCl and 0.1%sodium azide as preservative, and is provided in lyophilized.

Material Provided

1. 3 vials of controls with different levels:
   - Finecare™ cTnI/CK-MB/Myo Multi-Control Level 1: 1×0.5mL
   - Finecare™ cTnI/CK-MB/Myo Multi-Control Level 2: 1×0.5mL
   - Finecare™ cTnI/CK-MB/Myo Multi-Control Level 3: 1×0.5mL
2. 1 Leaflet with Instructions for Use

Material Required But Not Provided

Function	Material Name	Note
Test instrument	Finecare™ FIA Meter	Model No.: FS-112
	Finecare™ FIA Meter Plus	Model No.: FS-113
	Finecare™ FIA Meter II Plus SE	Model No.: FS-114
	Finecare™ FIA Meter III Plus	Model No.: FS-205
Test kit	Finecare™ cTnI/CK-MB/Myo Rapid Quantitative Test	Catalog No.:W216
Reconstitute the controls	Distilled water	/
Sampling	Transfer pipette set	/
	Medical gloves	Well-fitting
Disposal	Biohazard container	/
Timekeeping for specific test step	Timer	/

STORAGE AND STABILITY

1. Finecare™ cTnI/CK-MB/Myo Multi-Control is stable for 12 months when stored unopened at 2 ~ 8 °C and should keep away from sunlight.
2. Once reconstituted, the control will be stable for 8 hours when stored tightly capped at 2 ~ 30 °C.

TEST PROCEDURE

1. Take out the control from 2 ~ 8 °C and balance it at room temperature for 15 minutes before reconstituted.
2. Carefully reconstitute each vial of lyophilised control with exactly 0.5 mL distilled water.
3. Ensure contents are completely dissolved by swirling gently. Avoid the formation of foam.
4. The reconstituted control should be treated the same as patient specimen, and conduct the test procedures in accordance with the Instructions for Use of Finecare™

Digitally signed by Stoianova Elena
Date: 2025.11.26 09:45:14 EET
Reason: MoldSign Signature
Location: Moldova

cTnI/CK-MB/Myo Rapid Quantitative Test and the Operation Manual of Finecare™ FIA Meters.

VALUE ASSIGNMENT

The target value and range were derived from replicate analyses and are specific for this lot of product. The tests were performed by using manufacturer supported reagents and a representative sampling of this lot of product.

Value assignment:

Lot No. (Test Kit)	Lot No. (Control)	Level	cTnI(ng/mL)		CK-MB(ng/mL)		Myo(ng/mL)	
			Target Value	Range	Target Value	Range	Target Value	Range
		1						
		2						
		3						

INTERPRETATION OF RESULTS

The quality control product is measured on the calibrated test system, and the test values must be within the target ranges. Those outside the range may indicate unsatisfactory performance. Variations may be caused by techniques, instruments, test kits etc., which should be evaluated by the laboratory. Recommend that each laboratory should establish its own target ranges.

LIMITATIONS OF PROCEDURE

1. This product is applicable for Finecare™ cTnI/CK-MB/Myo Rapid Quantitative Test only.
2. This product is not intended for use as a calibrator or a standard.

PERFORMANCE CHARACTERISTICS

Precision

Intra-Vial Precision
Within-run precision has been determined by using 10 replicates of one vial control for each of three lots on the Finecare™ cTnI/CK-MB/Myo Rapid Quantitative Test. CV is ≤15%.
Inter-Vial Precision
Between run precision has been determined by using 10 different vials of controls for three lots on the Finecare™ cTnI/CK-MB/Myo Rapid Quantitative Test. CV is ≤15%.

BIBLIOGRAPHY OF SUGGESTED READING

[1] Horowitz M B, Willet D, et al. The Use of Cardiac Troponin-I (cTnI) to Determine the Incidence of Myocardial Ischemia and Injury in Patients with Aneurysmal and Presumed Aneurysmal Subarachnoid Hemorrhage[J]. Acta Neurochir (Wien), 1998, 140(1):87-93.
[2] Ricchiuti V, Apple F S. RNA expression of cardiac troponin T isoforms indiseased human-skeletal muscle[J]. Clin Chem, 1999, 45(12):2129-2135.
[3] Chocron S, Alwan W, et al. Effects of myocardial ischemia on the relase of cardic troponin I in isolated rat hearts[J]. J Thoras Cat-diovasc Surg, 1996, 112:508.
[4] Collinson P O, Stubbs P J, et al. Multicen tree valuation of the diagnostic value of cardiac troponin T, CK-MB mass, and myoglobin for assessing patients with suspected acute coronary syndromes in routine clinical practice[J]. Heart, 2003, 89(3): 280-286.
[5] Panteghini M, Cuccia C, et al. Single-point cardiac troponin T at coronary care unit discharge after myocardial infarction correlates with infarct size and ejection fraction [J]. Clin Chem, 2002, 48(9): 1432-1436.
[6] Sallach S M, Nowak R, et al.A change in serum myoglobin to detect acute myocardial infarction in patients with normal troponin I levels[J]. Am J Cardiol, 2004, 94(7):864-867.
7] Bekedam M A, van Beek-Harmsen B J, et al. Myoglobin concentration in skeletal muscle fibers of chronic heart failure patients[J]. J Appl Physiol, 2009, 107(4):1138-1143.
[8] Nitta T, Xundi X, et al. Myoglobin gene expression attenuates hepatic ischemia reperfusion injury. Journal of Surgical Research[J]. 2003, 110(2):322-331.

INDEX OF SYMBOLS

Consult instructions for use		CONTROL	Control
Date of manufacture		IVD	In vitro diagnostic medical device
Use-by date		REF	Catalogue number
Temperature limit			Keep away from sunlight
Keep dry			Manufacturer
LOT	Batch code	→	Volume after reconstitution or mixing
CE	CE marking	EC REP	Authorized representative in the European Community/ European Union

Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Huangpu District,
510663, Guangzhou, P.R.China
Tel: (+86) 400-830-8768
E-mail: Finecare@wondfo.com.cn
Website: en.wondfo.com

EC REP
Qarad BV
Cipalstraat 3
2440 Geel, Belgium

IFU-W817(1)-01-01
Version 03
2023/08/07

Wondfo®	文件编号 Document No.: IFU-W817(1)-01-01	版本Version: 03	项目名称：Leaflet with Instructions For Use	
	尺寸(长*宽*高)：142*210mm	颜色:	材质：双胶	工艺：/
	折页方式：十字折	修改内容：□文字 □颜色 □尺寸 □工艺 □材质 □其他 √无 修改内容截图		
	改稿前编码： /	申请人:	设计师：敖慧玲	设计时间：2023/08/07

稿件确认签名: