cTnI Control

REF QC001

User Manual

PRODUCT NAME

cTnI Control

PRODUCT SPECIFICATION

Package: 3(Level)*2(Vial)*1(ml), 3(Level)*1(Vial)*1(ml)
cTnI Control - Level 1/2/3

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of Cardiac Troponin I (cTnI) on the Getein Platforms.

PRINCIPLE

The lyophilized cTnI control is prepared from dissolving stable and high quality recombinant cTnI antigen into calf serum. With matching equipments and reagents, it can fulfill value transfer work. As different equipments and reagents have uncertainty to some extent, different control results may appear.

CONTENTS

The kit for FIA8000/FIA8600/Getein1100 contains:

1. cTnI Control - Level 1
   cTnI Control - Level 2
   cTnI Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box

The kit for Getein1600 contains:

1. cTnI Control - Level 1
   cTnI Control - Level 2
   cTnI Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box
4. Quality control holder - Level 1
   Quality control holder - Level 2
   Quality control holder - Level 3

Note: Each quality control holder is labelled with barcode which contains target value and level of different items.

MATCHING EQUIPMENTS

FIA8000/8600 Quantitative Immunoassay Analyzer
Getein1100/1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

UNOPENED: The product is stable for 18 months at -20℃ and for 30 days at 2 ~ 8℃ to avoid light.
OPENED: The product is stable for 1 day at 2 ~ 8℃ if kept capped in orginal container and free from contamination. Only the required amount of product should be removed. Any residual product should NOT BE RETURNED to the original vial after using. It is recommended to be dispensed into smaller vials after dilution and stable for 30 days at -20 ~ -70℃.

MATERIALS REQUIRED BUT NOT PROVIDED

1. 1 ml pipette
2. Distilled water
3. Getein test kit
4. Getein instrument

TEST PROCEDURE

1. The product should be brought to room temperature (15 ~ 30℃) prior to use.
2. Open the vial carefully in case of the loss of content.
3. Dissolve each control material with 1 ml distilled water.

4. Close the vial and mix gently until all contents are dissolved completely. Avoid violent shaking or foam formation.
5. Keep it at room temperature for 5 ~ 10 minutes before use.

For FIA8000/FIA8600/Getein1100:

6. Treat the control in the same manner as patient specimen in the assay procedure. Follow the directions of test kit and the instrument application instruction.

For Getein1600:

7. Insert quality control holder into sample holder.
8. Insert sample holder with a constant speed and barcode facing the scanner, refer to the User Manual of Getein1600 to start QC testing.

ASSIGNED VALUES

Refer to values listed on the target value sheet.
If the result is beyond the range, it indicates the existence of some unreliable factors in the testing system. Referring to the control graph helps judge the accuracy and stability of the testing system.
The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

PERFORMANCE CHARACTERISTICS

1. Homogeneity: ≤ 15%
2. Accuracy range: Refer to the target value sheet

LIMITATIONS

1. This product can only be used on the Getein Platforms.
2. Variation exists between different equipments developed by different methods even using the same control product.
3. This product is not intended to be used as standard material.

NOTES

1. For *in vitro* diagnostic use only.
2. Do not use the product beyond the expiration date.
3. Avoid multiple freeze-thaw cycles.
4. Do not use the product if it is contaminated with bacteria.
5. Proper handling and disposal methods should be followed in accordance with local regulations.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on cTnI control are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and EN ISO15223-1:2016.

Key to symbols used			
	Manufacturer		Expiration date
	Catalogue number		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		*In vitro* diagnostic medical device
	Sufficient for		Biological risk
	CE mark		Authorized representative in the European Community

Please read this user manual carefully before operating to ensure proper use.

Version: WZK01-S-04

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Digitally signed by Gangan Dumitru
Date: 2023.07.21 09:32:47 EEST
Reason: MoldSign Signature
Location: Moldova