

CARDIAC CONTROL - LEVEL I (CRD CONTROL I)

CAT. NO.	CQ10454	LOT NO.	4816CK
SIZE:	3 x 3 ml	EXPIRY:	2025-04-28
GTIN:	05055273217124		

INTENDED USE

The Cardiac Control Level I (CQ10454) is intended for use with in vitro diagnostic assays for the quantitative determination of Troponin I and NT-proBNP. Cardiac Control Level I is unassayed without target values and is suitable for use on automated analysers. Cardiac Control Level I is for use by trained laboratory professionals and can be used in determining the precision of testing systems and in identifying sources of variation.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

UNOPENED: Store at -20°C to -80°C. Stable to expiration date printed on individual vials.

OPENED: Store refrigerated (+2°C to +8°C). NT-proBNP and Troponin I are stable for 7 days at +2°C to +8°C, if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

PREPARATION

- 1. Allow the frozen control to thaw at room temperature (+15°C to +25°C) until completely thawed. Swirl the contents to ensure homogeneity.
- 2. Refer to the Control section of the individual analyser application.
- 3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED

Cardiac Control - Level I 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED Not applicable.

i vot applicable

ANALYTES NT-proBNP and Troponin I

VALUE ASSIGNMENT

Values should be assigned by each laboratory.

EC REP Randox Teoranta, Meenmore, Dungloe, Donegal, F94 TV06, Ireland

Rev. 17 Sep '24 me



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