

HIGH SENSITIVITY TROPONIN T CONTROL (HS TROPONIN T CONTROL)

CAT. NO. CQ5080 **LOT NO.** 3761CK
SIZE: 3 x 3 ml **EXPIRY:** 2018-11

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of Troponin T on clinical chemistry and Immunoassay systems.

DEVICE DESCRIPTION

Target values and ranges are supplied for Troponin T.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic 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

OPENED: Store refrigerated (+2°C to +8°C). Reconstituted serum is stable for 5 days at +2°C to +8°C, and 4 weeks at -20°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.

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

PREPARATION FOR USE

The Troponin T control is supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised serum with exactly 3 ml of redistilled water at +15°C to +25°C. Close the bottle and allow to stand for 30 minutes. Ensure contents are completely dissolved by swirling gently. Avoid the formation of foam. Do not shake.
2. Refer to the Control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED

High Sensitivity Troponin T Control 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette
Redistilled water

ASSIGNED VALUES

Values are assigned from internal testing conducted at Randox Laboratories Ltd. The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com

| Analyte | Target | Range | Method |
|---------------|-----------|------------------|---------------------|
| HS Troponin T | 11.1 ng/l | 8.33 - 13.9 ng/l | Roche hs Troponin T |

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