

PARTICIPANT INSTRUCTIONS

CARDIAC – CYCLE 36

Expiry date: 2020-01

Please check your kit upon arrival and call Thistle immediately if there are any problems with your kit or samples. We will advise you on the correct protocol to follow.

Introduction:

Method questionnaires are available for all the international Thistle programmes. It is important to read and understand this document. If you have any queries please contact Thistle QA immediately for assistance.

Method Questionnaire Instructions:

This is available on our website or on request from Thistle QA.

Method changes or new laboratories – take note of the information below:

The method questionnaire should be completed and a copy retained by you for your records. Ensure that you complete the method questionnaire in full. Your details will help us to classify your results correctly and thus provide you with useful statistical data.

The Method questionnaire consists of two separate documents:

- i. A list of laboratory analysers and supplier names, each with a numeric code, in order for you to select a code for each analyte. This document is called the Instrument and Suppliers list.
- ii. The method questionnaire, which indicates the method codes available for each parameter along with the standard unit indicated

On the method questionnaire, for each parameter you run, please tick the method appropriate to your lab. State your instrument code, reagent code, and the units that you use in your laboratory only if they are different to the standard units indicated. If codes are not available for your assay, please state the details of your method clearly in the section at the end of the questionnaire.

Characteristics:

Your pack contains lyophilised 1ml samples of human serum. The vials are labelled with a cycle and sample number.

Factors that could influence the testing of the sample

Important: Vials should be stored and transported at 2 - 8 °C.

After reconstitution, it is stable for 2 days at 2 - 8 °C.

Do not shake the vial.

Please treat as a routine patient sample.

Preparation:

The samples are sealed under vacuum. Open the vial very carefully, avoiding any loss of material and using a calibrated pipette reconstitute with an accurately measured 1ml volume of freshly double distilled water at **20 – 25 °C**. Replace the rubber stopper, close vial and leave to stand for 60 minutes out of bright light before use. Ensure complete dissolution by swirling gently. Do not shake the vial. Once reconstituted, please analyse the samples within 2 days.

Safety:

Warning: Potentially Biohazardous Material

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.

Return of Results:

Each of the samples has a number printed on the label. We recommend analysis dates as shown below. Please send your results **at the latest** - on the final cut-off dates given below. If the recommended analysis date does not allow you to get results to us on time, please analyse earlier. Use the correct dates for the sample numbers in the kit sent to your laboratory. If in doubt, please contact Thistle immediately for assistance. Late results will not be accepted after the final cut-off date.

Additional Notes:

Web site submission is available – please enter via web site using the user name and password given to you by Thistle QA. EDI system users must work through their relevant QA Divisions to ensure that results are imported in due time. The reports will be posted / e-mailed within 7-10 working days after the FINAL cut-off date. Collusion and/or falsification of EQA results are not good accreditation practice.

Return Dates for Results:

CARDIAC

<u>Sample No:</u>	<u>Analysis Dates:</u>	<u>Final Cut-off Dates:</u>
1	11 March 2019	18 March 2019
2	25 March 2019	01 April 2019
3	08 April 2019	15 April 2019
4	22 April 2019	29 April 2019
5	06 May 2019	13 May 2019
6	20 May 2019	27 May 2019
7	03 June 2019	10 June 2019
8	17 June 2019	24 June 2019
9	01 July 2019	08 July 2019
10	15 July 2019	22 July 2019
11	29 July 2019	05 August 2019
12	12 August 2019	19 August 2019