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PI-004

PLEASE NOTE THAT SAMPLES ARE LABELLED AS 9A
FOR WEBSITE OR EDI ENTRY USE CYCLE 9 ONLY

PARTICIPANT INSTRUCTIONS
IMMUNOASSAY SPECIALITY 1 – CYCLE 9

Expiry date: 2020-10

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 6 vials of lyophilised 2 ml samples. The vials are labelled with a sample number.

Factors that could influence the testing of the sample

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

The reconstituted sample is stable for 2 days at 2 - 8°C with the exceptions listed below.

Do not shake the vial

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. The samples should be treated in the same way as patient samples.

Preparation:

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The vial is sealed under vacuum. Open the vial very carefully, avoiding any loss of material and using a calibrated pipette reconstitute with an accurately measured 2ml volume of freshly double distilled water at 20°C - 25°C. Replace the rubber stopper and ensure that the sample is dissolved completely by swirling gently (ideally place on a roller for half an hour prior to analysis). **DO NOT SHAKE THE VIAL.** Once reconstituted, the samples should be analysed within 2 days with the following exceptions: **Parathyroid hormone (PTH) and ACTH (Adrenocorticotropic Hormone) should be analysed immediately after reconstitution. Osteocalcin should be tested within 4 hours of reconstitution. C-Peptide, IGF-1 and Procalcitonin should be analysed within 1 day of reconstitution.**

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.

For **IN VITRO DIAGNOSTIC** use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

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.

Additional Notes:

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

Sample No:	Analysis Dates:	Final Cut-off Dates:
1	07 January 2019	14 January 2019
2	04 February 2019	11 February 2019
3	04 March 2019	11 March 2019
4	01 April 2019	08 April 2019
5	06 May 2019	13 May 2019
6	03 June 2019	10 June 2019