

IMMUNOASSAY SPECIALITY 1 – CYCLE 2

Expiry date: 2012-10

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 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.

Follow the introductory pages:

- i. A list of laboratory analysers, each with a numeric code, in order for you to select a code for each analyte
- ii. A similar list of reagent suppliers, each with a numeric code, in order for you to select a code for each analyte
- iii. 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 enrolment document

Characteristics:

Your pack contains vials of lyophilised 2 ml samples. The vials are labelled with a sample number.

IMPORTANT: Vials should be stored at 2-8 °C

The reconstituted sample is stable for 2 days at 2 - 8°C.

N.B. C-Peptide and IGF-1 are stable for 1 day at 2 - 8°C and Osteocalcin and Parathyroid Hormone (PTH) are stable for 4 hours.

Please check your kit upon arrival and call Thistle immediately if there are any problems with your kit or samples. The samples should be treated in the same way as patient samples.

Preparation:

The vial is sealed under vacuum. Open the vial very carefully, avoiding any loss of material and reconstitute each one with an accurately measured 2ml volume of freshly distilled water. Replace the rubber stopper and ensure that samples are dissolved completely by swirling gently (ideally place on a roller for half an hour prior to analysis). **DO NOT SHAKE THE VIAL.**

Safety:

Warning: Potentially Biohazardous Material

The serum is human based. It has been source tested by FDA approved methods and found to be negative for HBsAg and antibodies to HIV and HCV. For complete protection however, it is recommended that the serum be handled as carefully as patient samples. Dispose of used samples as you would routine patient samples.

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 of the FINAL cut-off date.
Collusion and/or falsification of EQA results are not good accreditation practice.

Return Dates for Results: Immunoassay Speciality 1 – Cycle 2

<u>Sample No:</u>	<u>Analysis Dates:</u>	<u>Final Cut-off Dates:</u>
1	Please analyse sample 1 and submit results as soon as you receive your kit	
2	6 February 2012	13 February 2012
3	5 March 2012	12 March 2012
4	2 April 2012	09 April 2012
5	07 May 2012	14 May 2012
6	04 June 2012	11 June 2012