

IMMUNOASSAY – CYCLE 33

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 5 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 at least 3 days at 2 - 8°C or at least 8 hours at 15 - 25°C in the absence of bacterial contamination. Freshly reconstituted serum can be stored for up to 2 weeks at -20°C. Frozen aliquots should only be thawed once and tested as soon as thawing is complete.

Please check your kit upon arrival and call Thistle immediately if there are any problems with your kit or samples.

Preparation:

The vial is sealed under vacuum. Open it carefully and reconstitute with exactly 5 ml of freshly distilled water at room temperature. Replace the stopper and leave to stand for 30 minutes out of bright light before use. Ensure that the lyophilised contents are completely dissolved by swirling gently. **DO NOT SHAKE THE VIAL.**

Safety:

Warning: Potentially Biohazardous Material

The serum is human based. It has been source tested 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:

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 of the FINAL cut-off date.

Collusion and/or falsification of EQA results are not good accreditation practice.

<u>Sample No:</u>	<u>Analysis Dates:</u>	<u>Final Cut-off Dates:</u>
1	5 July 2010	12 July 2010
2	12 July 2010	19 July 2010
3	26 July 2010	2 August 2010
4	9 August 2010	16 August 2010
5	23 August 2010	30 August 2010
6	6 September 2010	13 September 2010
7	20 September 2010	27 September 2010
8	4 October 2010	11 October 2010
9	18 October 2010	25 October 2010
10	1 November 2010	8 November 2010
11	15 November 2010	22 November 2010
12	29 November 2010	6 December 2010