

CHEMISTRY – CYCLE 45

Expiry date: 2013-12

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

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:

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 lyophilised 5ml samples of human serum. The vials are labelled with a cycle and sample number.

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

After reconstitution, it is stable for 3 days at 2 - 8 °C or at least 8 hours at 15 - 25 °C.

Preparation:

Open the vial very carefully and reconstitute with an accurately measured 5ml volume of freshly distilled water at room temperature. Replace rubber stopper, close vial and leave to stand for 60 minutes out of bright sun light. Ensure complete dissolution by swirling gently. Do not shake the vial.

Prostatic & Total Acid Phosphatase: The samples can be stabilised by adding 1 drop of acetic acid to 1ml of serum.

Creatine Kinase: The measured level of CK can depend on the temperature of the distilled water used for reconstitution. Water at 20 – 25 °C is recommended. The sample should be analysed for CK within 1 - 2 hours after reconstitution.

Alkaline Phosphatase: Levels will rise over the stability period. It is recommended that the reconstituted serum be allowed to stand for 1 hour at room temperature before measurement and be analysed within 4 hours after reconstitution.

Bilirubin in the serum is light sensitive and it is recommended that the serum be stored in the dark before measurement. Bilirubin should be analysed within 8 hours of reconstitution.

Bacterial contamination of the reconstituted serum will cause reductions in the stability of many components.

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

Return Dates for Results:

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| <u>Sample No:</u> | <u>Analysis Dates:</u> | <u>Final Cut-off Dates:</u> |
|--------------------------|-------------------------------|------------------------------------|
| 1 | 12 September 2011 | 19 September 2011 |
| 2 | 26 September 2011 | 3 October 2011 |
| 3 | 10 October 2011 | 17 October 2011 |
| 4 | 24 October 2011 | 31 October 2011 |
| 5 | 7 November 2011 | 14 November 2011 |
| 6 | 21 November 2011 | 28 November 2011 |
| 7 | 5 December 2011 | 12 December 2011 |
| 8 | 19 December 2011 | 26 December 2011 |
| 9 | 2 January 2012 | 9 January 2012 |
| 10 | 16 January 2012 | 23 January 2012 |
| 11 | 30 January 2012 | 6 February 2012 |
| 12 | 13 February 2012 | 20 February 2012 |
| 13 | 27 February 2012 | 5 March 2012 |