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HUMAN URINE – CYCLE 37

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 10 ml samples. The vials are labelled with a sample number.

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

The sample is stable for 5 days at 2 - 8 °C in the absence of bacterial contamination with the exception of the analytes listed on the next page.

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 vial with exactly 10 ml of freshly distilled water at room temperature. Replace the stopper, close the vial and leave to stand for 30 minutes out of bright light. Ensure that all the lyophilised contents are completely dissolved by swirling gently.

DO NOT SHAKE THE VIAL.

Catecholamines, Metanephrines, VMA and Oxalate

These analytes are unstable in the reconstituted urine sample. Thirty minutes after complete reconstitution of the urine sample take a 3ml aliquot and add one drop of HCl from the HCl dropper bottle. The sample will be stable for 5 days at 2 - 8°C. For oxalate measurement it is recommended that EDTA be added to the urine sample at a concentration of 5mg/10ml material. This is to prevent the precipitation of Calcium Oxalate.

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5-Hydroxyindole acetic acid (5-HIAA)

This analyte is also unstable in the reconstituted urine sample. Thirty minutes after complete reconstitution of urine sample take a 2ml aliquot and add one drop of acetic acid from the acetic acid dropper bottle. The sample will be stable for 5 days at 2 - 8 °C. Acetic acid may solidify at 4 °C. To ensure complete liquidity of the acid please ensure the dropper bottle contents are brought to room temperature prior to use.

- **Please note that if Nitroso-Naphthol method is used for 5-HIAA, one drop of HCl from the HCl dropper bottle should be added to a 2 ml aliquot of reconstituted urine. The addition of HCl is also recommended where 5-HIAA is assayed using HPLC methods with prior extraction.**

Vitros Users:

These are recommendations from Ortho-Clinical Diagnostics:

- Do not pre-treat the reconstituted fluid.
- Ensure that the correct dilution and diluents are used (see method sheet) and that samples are mixed well.
- Make sure that the sample is run using the urine calibration on the system.
- No adjustment to results is carried out.

Safety:

Warning: Potentially Biohazardous Material

The sample contains lyophilised human urine and should be handled with the same precautions used for patient specimens, which may contain potentially infectious agents. 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.

Sample No:	Analysis Dates:			Final Cut-off Dates:		
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