

HBA1C – CYCLE 6

Expiry date: 2012 - 08

Please note that sample 1 results are due immediately upon receipt of your kit.

Introduction:

Method questionnaires are available for all Thistle programmes. It is important to read and understand this document. If you have any queries please contact Thistle QA immediately for assistance.

Characteristics:

Your pack contains 6 vials of lyophilised 0.5 ml samples. Each vial is labelled with the cycle, sample number and the date of analysis. **Please check your kit upon arrival and call Thistle immediately if there are any problems with your kit or samples.**

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

Preparation

1. The samples are sealed under vacuum. Open the vial carefully, avoiding any loss of material and reconstitute with an accurately measured **0.5ml** volume of freshly distilled water at room temperature.
2. Replace the sample cap, swirl the vial several times and leave to stand at room temperature for **15 minutes**.
3. After 15 minutes coat all surfaces of the bottle by rotating and inverting the vial. Continue mixing until the solution is homogenous and all lyophilised material is reconstituted. Do not shake the vial.
4. The reconstituted sample is stable for **1 month** when stored refrigerated at **2 - 8°C**. Do not freeze the reconstituted samples.

NB. The reconstituted samples should be treated the same as patient samples. Depending on the method of analysis, they may require pre-treatment (either on the analyser or manually) in order to assay for HbA1c.

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, HIV2) 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 disease 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:

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.

Return Dates for Results:

<u>Sample No:</u>	<u>Analysis Dates:</u>			<u>Final Cut-off Dates:</u>		
1	10	January	2011	17	January	2011
2	14	February	2011	21	February	2011
3	14	March	2011	21	March	2011
4	11	April	2011	18	April	2011
5	9	May	2011	16	May	2011
6	13	June	2011	20	June	2011