

RIQAS

RANDEX INTERNATIONAL QUALITY ASSESSMENT SCHEME

**METHOD QUESTIONNAIRE
GLYCATED HAEMOGLOBIN
(HbA_{1c}) PROGRAMME**

This document must be retained by participant

REGISTRATION INSTRUCTIONS & RIQAS POLICIES

CRITERIA FOR PARTICIPATION

This programme is available to any laboratory running a Glycated Haemoglobin assay as listed in this document. Quantitative results will be accepted on this programme.

INTRODUCTION

Method questionnaires are available for all routine *RIQAS* Programmes. They are designed to allow you to register for this *RIQAS* Programme and to inform you of *RIQAS* protocols and policies. It is important that you read and understand all the information in these introductory pages. If you have any questions or concerns about any of the information presented in this document, please contact *RIQAS* either directly or through your local Randox Laboratories representative.

REGISTRATION INSTRUCTIONS

1. METHOD QUESTIONNAIRE:- To be retained by participant

This method questionnaire should be completed and retained by you for your records. Please 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.

Following these introductory pages you will find:

The method questionnaire, which indicates the method codes available for each parameter along with the standard *RIQAS* unit.

On the method questionnaire, for each parameter you wish to run, please tick the method appropriate to you, then state your instrument code, reagent code, and the units that you use in your laboratory if they are different from the *RIQAS* standard units. 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.

It is important that you register appropriately according to the alignment of your results to IFCC of DCCT/NGSP standards. If your results are not reported to either of these, please register in the Non-aligned group,

Once your method questionnaire has been completed, you must transfer the information onto your enrolment document.

2. ENROLMENT DOCUMENT:- To be returned to *RIQAS*

Please be aware that it may take up to 3 weeks to process enrolment documents.

A. LABORATORY REFERENCE NUMBER

Each participant is assigned a **laboratory reference number** which consists of a **participant number** which is unique to your laboratory and a **registration letter** which is assigned for each new registration we receive from you. If you are a current or previous participant, please state your **participant number** on the enrolment document. If you do not have a Laboratory Reference Number, this will be generated by *RIQAS* when you register for the first time.

B. ORDER NUMBER

If you are a UK or Irish participant, please state your official order number in the boxes provided. Other participants may order directly from their local Randox Laboratories representative.

C. CYCLE/PRODUCT REQUIREMENTS

Please tick the cycles you wish to subscribe for. If there is more than one kit/product offered for the programme, please also tick the kit you wish to subscribe for.

D. CONTACT DETAILS

It is important to state the name and full address details of the Quality Assessment Officer or contact person who will receive all correspondence and routine reports during the cycle. Please also state the company name of the Randox representative who is supplying you with the *RIQAS* product under 'Randox Representative'.

E. *RIQAS* Net

An alternative to e-transfer, *RIQAS* Net is a web-based online method for result entry/method changes/viewing of released reports. Reports will be sent to up to 3 email addresses as PDF files. Internet access and login details are required for *RIQAS* Net and Adobe Reader is required for viewing reports. If you wish to use *RIQAS* Net please indicate this by ticking the box on the enrolment document. Your login information and password will be supplied by *RIQAS*. Your login information will be based on the 1st email address you supply on your enrolment document. A PDF copy of the report will be sent to this address and can also be sent to 2 other email addresses. These addresses should be stated on your enrolment document.

F. PDF reports

Reports can now be sent as PDF files as an alternative to paper reports. These files can be sent to up to 3 email addresses. If you wish to receive PDF reports please indicate this by ticking the box on the enrolment document and include the email addresses to which the reports should be sent. Adobe Reader is required to view the reports.

G. E-TRANSFER

If you wish to send results and receive reports electronically using the *RIQAS* e-transfer software please contact your local Randox representative. You will be supplied with a copy of the software and instructions for installation and use. **If you wish to use e-transfer, please indicate this by ticking the box on the enrolment document and include the email address that will be used for e-transfer.** You will be issued with a laboratory reference number for each enrolment. Please enter your laboratory reference number(s) into the registration form on your e-transfer software and e-mail it to returns@riqas.com. Following registration, you will receive a look up table (.tbl file) containing information required to activate your software.

H. GROUP REPORTS

It is possible to enrol **multiple instruments** within your laboratory. **Kindly complete separate enrolment documents for each instrument.** A **complementary instrument group report** is supplied if you have returned results for more than one registration of the same programme. If you intend to enrol laboratories at different sites or if you are part of a group of laboratories, an **inter-laboratory group report for each sample** can be supplied on receipt of a completed authorisation form from each registered laboratory. Please contact *RIQAS* for a copy of the official inter-laboratory authorisation form.

I. REGISTRATION OF METHODS

Complete the 'Registration of Methods' section for all required parameters using the codes you selected on your method questionnaire. If no code is available for your assay, please state the details of your method clearly in the section at the end of the enrolment document.

For Ortho-Clinical Diagnostics VITROS registrations, please state the 2 digit slide Generation number for each analyte.

If units other than the standard RIQAS units are used, please specify these in the boxes supplied.

Once completed, the enrolment document should be sent to RIQAS for registration.

NOTE: IF A REGISTERED PARTICIPANT DOES NOT PARTICIPATE FOR A CYCLE, THEY WILL BE EXPECTED TO COMPLETE NEW ENROLMENT DOCUMENTS IN ORDER TO RE-JOIN THE PROGRAMME.

J. CHANGES DURING A CYCLE

Please inform *RIQAS* of any change to contact details as soon as possible. It is also possible to change your unit, method, instrument or reagent classification during a cycle.

Participants who use return sheets: Each Results Return Sheet has a section for method changes. Please state your new classification codes at the bottom of your next return sheet. We assume that your new classification will be in routine use from the date on the return sheet unless you tell us otherwise. If you have added or deleted a parameter, changed your unit or Vitros slide generation number, an updated return sheet will be forwarded to you. It is important that you discard your old return sheet and use only your updated copy for future returns.

Participants who use e-transfer: Changes can be made in the Method Changes section of the Data Entry menu. Select the appropriate lab reference number, choose the appropriate details from the drop-down headers, indicate the cycle and sample from which the change is to be initiated, then tab off the line to save. You can simultaneously send Method Changes and Results to *RIQAS*. *RIQAS* staff will update your assay details and send a new look-up table, which must be saved into your \riqas\email folder in order to update your software with the new assay details.

Participants who use RIQAS Net: Changes can be made in the Method Changes section of the Data Entry menu. A list of your registered laboratory reference numbers will appear on screen. Select the laboratory reference number for which you would like to change the assay details. A current list of assay details will appear. Click on the appropriate parameter and the assay details will appear. To change the details click the arrow box on the appropriate details and select a new one. Save the changes and submit them to *RIQAS*. Changes will not be instantaneously updated. On receipt of method changes *RIQAS* staff will manually process and update your assay details which will then be uploaded onto *RIQAS* Net. It is possible to submit results and method changes at the same time as method changes will be made before results are submitted.

LABORATORY REFERENCE NUMBERS, RETURN SHEETS & LOOK-UP TABLES

On receipt of your enrolment document *RIQAS* will generate a **Laboratory Reference Number** for your laboratory and additional numbers for associated laboratories or multiple instruments if requested. If you are registering for the first time you will be sent *RIQAS* literature, which will enable you to understand the *RIQAS* process and interpret your reports.

E-transfer participants will be issued with a laboratory reference number for each enrolment. Please enter these details into the registration form on your e-transfer software and e-mail it to returns@riqas.com. Following registration, you will receive a look up table (.tbl file) containing details to activate your software and enable you to enter results, send them to *RIQAS* and view reports received from *RIQAS*.

Participants using *RIQAS* Net will receive an email containing their login information. Once you have successfully logged in to *RIQAS* Net you will see your various laboratory reference numbers for each registered programme.

Participants who do not use e-transfer or *RIQAS* Net will be sent a master return sheet which is specific for your registered parameters and units. You should photocopy this sheet as required and use it to return results to *RIQAS*.

ORDERING RIQAS PRODUCTS

Please ensure that your order is placed with your local Randox representative **at least 6-8 weeks** before the cycle starts. This will ensure sufficient time to process and despatch your kit(s) to you. Participants from UK or Ireland may order products directly from *RIQAS* with an official order number. Orders received within 6 weeks of the start of the cycle will be processed, but *RIQAS* cannot guarantee delivery in time for the first sample. Current prices of *RIQAS* products are available from your local Randox Laboratories representative.

It may be possible to order *RIQAS* products during a cycle, subject to availability. Please contact your local Randox representative for more information.

SHIPPING AND RECEIPT OF RIQAS PRODUCTS

Provided that you have ordered sufficiently in advance, your *RIQAS* kit(s) will be shipped to you to arrive before the analysis date of the first sample in the kit. If you do not receive your kit(s) before this time, please contact your local Randox representative.

On receipt of your *RIQAS* kit, please check that:

- a) it is the product you ordered
- b) the tamper-proof label has not been broken
- c) the kit contains detailed Instructions For Use (IFU), including material characteristics, preparation, stability, storage and safety
- d) the correct number of samples are present as indicated on the IFU
- e) the samples have the appearance as indicated on the IFU and that none of them are damaged

Please notify your local Randox representative immediately if any of these are incorrect.

Please ensure that the product is immediately stored according to the recommendations on the package labelling.

ASSAY OF SAMPLES & RETURN OF RESULTS

Carefully read the instructions stated on the Instructions for Use (IFU) prior to preparation and assay of *RIQAS* samples. The *RIQAS* samples should be assayed at the recommended time specified on the IFU. Following appropriate preparation, samples should be treated as routine, unless otherwise stated on the IFU. Please assay the samples on or before the recommended date for analysis and forward your results to *RIQAS* by no later than **17:00 GMT on the FINAL DATE**, as indicated in the IFU. If returning results on return sheet, it is most important that your Laboratory Reference Number(s), cycle number, sample number and FINAL DATE for return of results are clearly written at the top of the return sheet. If you wish to fax your results please transmit them 3 working days before the FINAL DATE to + 44 (0) 28 9445 4398. You may also e-mail your results to mail@riqas.com. Please contact *RIQAS* for a RESULT RETURN SHEET template.

LATE AND CORRECTED RESULTS

In keeping with the objectives of EQA schemes, participants should be aware that collusion and falsification of results is considered to be unethical and constitutes scientific fraud. While *RIQAS* permits the submission of late or corrected results under the circumstances described below, routine reports are clearly marked to indicate late and corrected results.

LATE RESULTS

Results received after the FINAL DATE will be processed retrospectively. Participants will still receive their report which will record late results as "NO RESULTS" until reprocessing is complete. Please ensure that any late results you wish to submit reach us by no later than the final date of the following sample. Any results received after this date will not be entered.

CORRECTED RESULTS

Participants will be permitted to submit corrected results up to 4 weeks after the final date of the sample. While a new report will not be issued, corrected results will be processed retrospectively and results can be viewed on subsequent reports.

DESPATCH OF REPORTS

Results will normally be processed within 2 days of the FINAL DATE. Reports sent by e-transfer are despatched as soon as the results have been processed. PDF reports will also be sent as soon as the results have been processed and for those registered for *RIQAS* Net the PDF reports will be available on *RIQAS* Net shortly after. Printed reports usually take a further 1-3 days to print and despatch.

CERTIFICATES OF PARTICIPATION

Complimentary certificates of participation for each *RIQAS* programme are available to participants at the **end of the current cycle**, provided that **at least 50%** of results have been returned. The certificate will specify the cycle, programme and the LABORATORY / HOSPITAL NAME specified in the address details of the enrolment document. Modified certificates may be requested through your local Randox representative. At the end of a cycle, a list of all eligible labs will be sent to the local Randox representative who will confirm the Laboratory/Hospital Name. This list will be returned to the *RIQAS* department and certificates printed according to the details sent by the local Randox representative. If any modifications or additions are required after this list has been finalised an administration fee will be charged.

CONFIDENTIALITY

Participation in any *RIQAS* programme is considered to be strictly confidential. Any data transfer or correspondence with participants, either directly or via local Randox representative, will be deemed confidential. Participants should be aware that their laboratory accreditation bodies have the right to request an assessment of a participant's performance. Where regulatory authorities are to be provided with a participant's results, participants will be notified.

PERFORMANCE SURVEILLANCE OF UK LABS

RIQAS is obligated to identify and report persistent poor performing UK labs to the National Quality Assessment Advisory Panel. Poor performers are identified as those failing to meet performance criteria agreed with NQAAP. The performance criteria is specified in all performance surveillance correspondence with participants, and is also available on request. Participants are initially informed of poor performance by letter. Failure to improve performance will prompt details to be forwarded to NQAAP. All information sent to participants and NQAAP is strictly confidential. Please contact *RIQAS* if you require further information on Performance Surveillance.

PARTICIPANT FEEDBACK & RIGHT TO APPEAL

In order to ensure that *RIQAS* provides an appropriate and satisfying service, all participants will be provided with a feed-back questionnaire towards the end of a cycle. We would invite you to contact us at any time during the cycle, should you have any requests for additional programmes or parameters or comments regarding existing programmes.

RIQAS makes every effort to ensure that the samples provided are clinically challenging to as many laboratory systems as possible. For details, please contact *RIQAS* either directly or through your local Randox representative.

Should the need arise, participants may appeal against the interpretation of their results or assessment of their performance through correspondence with the local Randox Laboratories representative or by contacting *RIQAS* directly.

SUB-CONTRACTING

RIQAS sub-contracts aspects of this programme. *RIQAS* accepts responsibility for the sub-contractors' work and protocols are in place to ensure that sub-contractors are deemed competent.

OUR COMPETENCE AS A PROFICIENCY TESTING PROVIDER

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DEVIATION FROM EXISTING POLICIES/SERVICE

If there is any deviation from the existing policies or service, participants will be notified either directly or via their local Randox representative.

Please contact RIQAS at

Tel: +44 (0) 28 9445 4399

Fax: +44 (0) 28 9445 4398

E-Mail mail@riqas.com

e-transfer returns@riqas.com

RIQAS Scheme Co-ordinator: Stephen Doherty

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THIS PROGRAMME IS ACCREDITED BY UKAS TO ILAC

G13:08/2007



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GLYCATED HAEMOGLOBIN (HbA_{1c})

METHOD QUESTIONNAIRE

HbA_{1c} results aligned to DCCT / NGSP (%)

CODE	METHOD
GDAER	<input type="checkbox"/> Abbott Aeroset
GDARC	<input type="checkbox"/> Abbott Architect c/ci Systems
GDABX	<input type="checkbox"/> Abbott Axsym
GDPEN	<input type="checkbox"/> ABX Pentra
GDACE	<input type="checkbox"/> Alfa Wasserman ACE/spACE/NExCT
GDOL	<input type="checkbox"/> Beckman Coulter AU400 / 600 / 640 / 2700 / 5400
GDDXC	<input type="checkbox"/> Beckman DxC600/DxC800
GDCX	<input type="checkbox"/> Beckman Synchron CX4/5/7/9
GDLX	<input type="checkbox"/> Beckman Synchron LX20/PRO
GDTEN	<input type="checkbox"/> Biorad D-10
GDDIA	<input type="checkbox"/> Biorad Diastat
GDMIC	<input type="checkbox"/> Biorad Micromat II
GDVA	<input type="checkbox"/> Biorad Variant I
GDVAB	<input type="checkbox"/> Biorad Variant II (Boronate Affinity)
GDVA2	<input type="checkbox"/> Biorad Variant II (ion exchange)
GDB25	<input type="checkbox"/> Biosystems A15/A25
GDDS5	<input type="checkbox"/> Drew DS5/G15
GDHBG	<input type="checkbox"/> Drew Hb-Gold
GDEC	<input type="checkbox"/> Erba-Chem EC-5
GDH7	<input type="checkbox"/> Hitachi 7 series
GDH9	<input type="checkbox"/> Hitachi 9 series
GDAG	<input type="checkbox"/> HP Agilent 1100
GDHUM	<input type="checkbox"/> Human Autohumalyser
GDIL	<input type="checkbox"/> ILab 600/Monarch
GDMIV	<input type="checkbox"/> I.S.E. srl Mivra
GDKON	<input type="checkbox"/> Konelab 20/30/60
GDHA	<input type="checkbox"/> Menarini HA8121/8140/8160
GDMM	<input type="checkbox"/> Merck Microlab
GDMR	<input type="checkbox"/> Milton Roy, Spectronic
GDMIN	<input type="checkbox"/> Mindray BS200/300/400
GDNYC	<input type="checkbox"/> Nycocard Reader
GDFUS	<input type="checkbox"/> Ortho Vitros 5.1 FS
GDO	<input type="checkbox"/> Other analysers
GDPRI	<input type="checkbox"/> Primus CLC385 / PDQ / Ultra 2
GDRXD	<input type="checkbox"/> Randox Rx Daytona
GDCOB	<input type="checkbox"/> Roche Cobas 6000
GDMIR	<input type="checkbox"/> Roche Cobas Mira
GDGDx	<input type="checkbox"/> Roche GDx (Boronate Affinity)
GDINT	<input type="checkbox"/> Roche Integra
GDMOP	<input type="checkbox"/> Roche Modular P
GDADV	<input type="checkbox"/> Siemens/Bayer ADVIA 1200/1650/2400
GDDCA	<input type="checkbox"/> Siemens/Bayer DCA2000
GDRA	<input type="checkbox"/> Siemens/Bayer RA50
GDDD	<input type="checkbox"/> Siemens/Dade Dimension
GDTOS	<input type="checkbox"/> TOSOH HLC723/G7
GDFLX	<input type="checkbox"/> Vitalab Flexor

GLYCATED HAEMOGLOBIN (HbA_{1c})

METHOD QUESTIONNAIRE

HbA_{1c} results aligned to IFCC (%)

CODE	METHOD
GIAER	<input type="checkbox"/> Abbott Aeroset
GIARC	<input type="checkbox"/> Abbott Architect c8000/ci8000
GIPEN	<input type="checkbox"/> ABX Pentra
GIACE	<input type="checkbox"/> Alfa Wasserman ACE/spACE/NExCT
GIOL	<input type="checkbox"/> Beckman Coulter AU400 / 600 / 640 / 2700 / 5400
GICX	<input type="checkbox"/> Beckman Synchron CX4/5/7/9
GILX	<input type="checkbox"/> Beckman Synchron LX20/PRO
GITEN	<input type="checkbox"/> Biorad D-10
GIDIA	<input type="checkbox"/> Biorad Diastat
GIMIC	<input type="checkbox"/> Biorad Micromat II
GIVA	<input type="checkbox"/> Biorad Variant I
GIVA2	<input type="checkbox"/> Biorad Variant II
GIBS	<input type="checkbox"/> Biosystems A15
GIDS5	<input type="checkbox"/> Drew Ds5/G15
GIHBG	<input type="checkbox"/> Drew Hb-Gold
GIEC	<input type="checkbox"/> Erba-Chem EC-5
GIH7	<input type="checkbox"/> Hitachi 7 series
GIH9	<input type="checkbox"/> Hitachi 9 series
GIAG	<input type="checkbox"/> HP Agilent 1100
GIHUM	<input type="checkbox"/> Human Autohumalyser
GIIL	<input type="checkbox"/> ILab 600/Monarch
GIKON	<input type="checkbox"/> Konelab 20/30/60
GIHA	<input type="checkbox"/> Menarini HA8121/8140/8160
GIMM	<input type="checkbox"/> Merck Microlab
GIMR	<input type="checkbox"/> Milton Roy, Spectronic
GIMIN	<input type="checkbox"/> Mindray BS200/300/400
GINYC	<input type="checkbox"/> Nycocard Reader
GIFUS	<input type="checkbox"/> Ortho Vitros 5.1 FS
GIO	<input type="checkbox"/> Other analysers
GIPRI	<input type="checkbox"/> Primus CLC385 / PDQ / Ultra 2
GIRXD	<input type="checkbox"/> Randox Rx Daytona
GICOB	<input type="checkbox"/> Roche Cobas 6000
GIMIR	<input type="checkbox"/> Roche Cobas Mira
GIGDX	<input type="checkbox"/> Roche GDx (Boronate Affinity)
GIINT	<input type="checkbox"/> Roche Integra
GIMOP	<input type="checkbox"/> Roche Modular P
GIADV	<input type="checkbox"/> Siemens/Bayer ADVIA 1200/1650/2400
GIDCA	<input type="checkbox"/> Siemens/Bayer DCA2000
GIRA	<input type="checkbox"/> Siemens/Bayer RA50
GIDD	<input type="checkbox"/> Siemens/Dade Dimension
GITOS	<input type="checkbox"/> TOSOH HLC723/G7
GIFLX	<input type="checkbox"/> Vitalab Flexor

GLYCATED HAEMOGLOBIN (HbA_{1c})

METHOD QUESTIONNAIRE

Non-aligned HbA_{1c} results (%)

CODE	METHOD
GNAER	<input type="checkbox"/> Abbott Aeroset
GNARC	<input type="checkbox"/> Abbott Architect c8000/ci8000
GNPEN	<input type="checkbox"/> ABX Pentra
GNACE	<input type="checkbox"/> Alfa Wasserman ACE/spACE/NExCT
GNOL	<input type="checkbox"/> Beckman Coulter AU400 / 600 / 640 / 2700 / 5400
GNCX	<input type="checkbox"/> Beckman Synchron CX4/5/7/9
GNLX	<input type="checkbox"/> Beckman Synchron LX20/PRO
GNTEN	<input type="checkbox"/> Biorad D-10
GNDIA	<input type="checkbox"/> Biorad Diastat
GNMIC	<input type="checkbox"/> Biorad Micromat II
GNVA	<input type="checkbox"/> Biorad Variant I
GNVA2	<input type="checkbox"/> Biorad Variant II
GNDS5	<input type="checkbox"/> Drew DS5/G15
GNHBG	<input type="checkbox"/> Drew Hb-Gold
GNEC	<input type="checkbox"/> Erba-Chem EC5
GNH7	<input type="checkbox"/> Hitachi 7 series
GNH9	<input type="checkbox"/> Hitachi 9 series
GNAG	<input type="checkbox"/> HP Agilent 1100
GNHUM	<input type="checkbox"/> Human Autohumalyser
GNIL	<input type="checkbox"/> ILab 600/Monarch
GNKON	<input type="checkbox"/> Konelab 20/30/60
GNHA	<input type="checkbox"/> Menarini HA8121/8140/8160
GNMM	<input type="checkbox"/> Merck Microlab
GNMR	<input type="checkbox"/> Milton Roy, Spectronic
GNMIN	<input type="checkbox"/> Mindray BS200/300/400
GNNYC	<input type="checkbox"/> Nycocard Reader
GNFUS	<input type="checkbox"/> Ortho Vitros 5.1 FS
GNO	<input type="checkbox"/> Other analysers
GNPRI	<input type="checkbox"/> Primus CLC385 / PDQ / Ultra 2
GNRXD	<input type="checkbox"/> Randox Rx Daytona
GNCOB	<input type="checkbox"/> Roche Cobas 6000
GNMIR	<input type="checkbox"/> Roche Cobas Mira
GNGDX	<input type="checkbox"/> Roche GDx (Boronate Affinity)
GNINT	<input type="checkbox"/> Roche Integra
GNMOP	<input type="checkbox"/> Roche Modular P
GNADV	<input type="checkbox"/> Siemens/Bayer ADVIA 1200/1650/2400
GNDCA	<input type="checkbox"/> Siemens/Bayer DCA2000
GNEXP	<input type="checkbox"/> Siemens/Bayer Express Plus
GNRA	<input type="checkbox"/> Siemens/Bayer RA50
GNDD	<input type="checkbox"/> Siemens/Dade Dimension
GNTBS	<input type="checkbox"/> Tokyo Boeki/Prestige 24i
GNTOS	<input type="checkbox"/> TOSOH HLC723/G7
GNFLX	<input type="checkbox"/> Vitalab Flexor
