RIQAS

RANDOX INTERNATIONAL QUALITY ASSESSMENT SCHEME

METHOD QUESTIONNAIRE
GLYCATED HAEMOGLOBIN
($HbA1_c$) PROGRAMME
RQ9129

Please be aware that the RIQAS Instrument and reagent supplier codes are now in a separate booklet. Please ensure you have a copy of this in order to complete this document.

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 except those using instrument 611 - Axis-Shield Afinion. Quantitative results will be accepted on this programme.

INTRODUCTION

Method questionnaires are available for all routine RIQAS Programmes and are reviewed and updated every month, as indicated by the issue date at the bottom of every page. 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 before completing the enrolment document, which forms the basis of your registration and contract with RIQAS. 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. RIQAS Calendar dates and information about the RIQAS portfolio of products can be found on www.randox.com/riqas-external-quality-assessment.

REGISTRATION INSTRUCTIONS

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.

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.

In order to fully complete this questionnaire you will also need a copy of the RIQAS Instruments and Reagent Suppliers which is available to download from the Randox website (www.randox.com/riqas-external-quality-assessment). Please ensure you have this list available when completing this questionnaire.

Following this introduction section, is 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.

NB. It is important that you register appropriately according to the ***alignment of your results*** to IFCC or 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.

ENROLMENT DOCUMENT:- To be returned to RIQAS

Please be aware that it may take up to 3 weeks to process enrolment documents if you are not entering your own assay details. When registering RIQAS enrolment documents, it is recommended that you state business contact details, rather than personal.

A. LABORATORY REFERENCE NUMBER

On receipt of an enrolment document, 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 and you will be sent RIQAS literature, which will enable you to understand the RIQAS process and interpret your reports. Please quote this number on all correspondence with RIQAS.

B. GROUP REPORTS

It is possible to enrol multiple instruments within your laboratory. Kindly complete separate enrolment documents for each instrument clearly identifying each instrument in the box provided. 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.

C. 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.

D. 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.

E. PRIMARY CONTACT DETAILS

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

Please inform RIQAS of any change to contact details as soon as possible.

F. RIQASNet

RIQASNet is a web-based online method for result entry / method changes and additions of parameters / viewing of released reports. To access RIQASnet go to www.riqas.net. Internet access and login details are required for RIQASNet and Adobe Reader is required for viewing reports. Your initial login information and password will be supplied by RIQAS. Once you have logged in for the first time you will be able to change your RIQASNet password. If you forget your password please follow the 'Forgotten Password' link. 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.

G. PDF REPORTS

Reports are sent as PDF files. These files can be sent to up to 3 email addresses. Adobe Reader is required to view the reports. The email addresses to which reports are sent can be reviewed and changed on RIQASNet.

H. SUMMARY CSV FILES

Labs can register to receive a csv file which contains a summary of your routine report statistics and performance indicators. This file mirrors the information found on the summary page of your report, except that we have included the calculated SD and SDPA. Also the PERFORMANCE column will show * in place of the red triangle usually shown on the summary page of your routine report. This can be sent to the 3 email addresses registered to receive the pdf reports. If you wish to receive a summary csv file please indicate this by ticking the box on the enrolment document and include the email addresses to which the reports should be sent. CSV files are also available for Instrument and Inter-Laboratory group reports. Please contact RIQAS for further information.

I. CUSTOMER DECLARATION

The declaration indicates that by submitting your enrolment document to RIQAS, either directly or via your local Randox representative, you have read and understood the RIQAS policies stated in the most recent Method Questionnaire associated with this programme. You understand that the submission of your enrolment document to RIQAS marks the beginning of an on-going agreement, and you will be automatically enrolled in subsequent cycles of this programme until we receive written confirmation of your cancellation. This should be received 12 weeks prior to the month in which the cycle starts. You understand that you must inform RIQAS of any changes to your contact details, assay details or contract status. You authorise Randox Laboratories Ltd. to send communication related to the products and service provided to the e-mail or postal addresses stated on your submitted enrolment document. You understand that you are permitted to request disclosure of, change or erase personal details held by Randox Laboratories Ltd. at any time. Note: Method questionnaires are updated every month and the issue date is stated on every questionnaire and enrolment document.

J. REGISTRATION OF ASSAY DETAILS

Labs can register their assay details using RIQASNet or can complete the 'Registration of Assay Details' section of the enrolment document. Labs should tick the appropriate box under the 'Registration of Assay Details' section of the enrolment document. If a lab wishes RIQAS to register their assay details, they should complete the Registration of Assay Details section using the codes from this method questionnaire and the Instrument/Reagent Supplier Book.

Once a participant has registered they will receive an email containing their RIQASNet login information. Once you have successfully logged in to RIQASNet you will see your various laboratory reference numbers for each registered programme. If you have opted to add parameters/assay details using RIQASNet, please do so as soon as possible (see below).

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 or follow the instructions on RIQASNet.

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.**

K. UPDATING ASSAY DETAILS

It is possible to change your unit, method, instrument or reagent classification during a cycle.

Method changes via RIQASNet: These can be made in the Assay Details 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. 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 RIQASNet but will be uploaded onto RIQASNet usually within 72 hours. It is possible to submit results and method changes together as method changes will be made before results are entered in to the RIQAS database.

L. ADDITION OF PARAMETERS / ASSAY DETAILS

Adding Parameters via RIQASNet: Parameters can be added using the Assay Details 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 add the assay details. At the top of the screen is 'Add Parameter'. Click on this and a list of parameters you are not registered for will appear. Select the parameter you wish to add and click the arrow box on the appropriate details and select your assay details. Save the changes and submit them to RIQAS. As above, additions will be available on RIQASnet usually within 72 hrs.

NB Deletions of parameters cannot be made on RIQASNet. If you wish to delete a parameter please contact RIQAS directly on mail@riqas.com.

ORDERING RIQAS PRODUCTS

Please ensure your purchase order for each cycle is placed with your local Randox representative 12 weeks prior to the month in which 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 12 weeks of the start of the cycle will be processed with an additional administration fee. 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 kit contains detailed Instructions For Use (IFU), including material characteristics, preparation, stability, storage and safety
c) the correct number of samples are present as indicated on the IFU
d) 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. **These are available on RIQASNet only.** 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. Results are submitted via RIQASNet, which can be accessed once you have received log in details via email. This will include a link to RIQASNet Instructions for Use.

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. RIQAS policies must ensure that a laboratory is unaware of RIQAS means for comparison before submitting their own results. Where a result is not submitted by the final date, a report will be issued, but the missing results will be indicated as “No return” or “N” throughout the RIQAS reports. RIQAS permits the submission of late or corrected results only under the circumstances described below. Requests for the submission of late or corrected results must be submitted in writing and in English on RIQAS Form No. 9277-RQ (either by the participant or their local Randox Representative) and must be approved by RIQAS Management. The form is available on www.riqas.net.

Requests for the submission of late results must be accompanied by evidence that an error has been made, and that the error has not been caused by the participant.

Requests for the correction or removal of erroneous results must be accompanied by evidence that the error was non-analytical, as defined on form 9277-RQ. RIQAS is obliged to inform country-specific regulatory bodies of requests for correction of results (if they request such information for laboratory monitoring purposes).

New reports will be re-issued for late or corrected results only where there has been an error made by Randox Laboratories HQ, Randox representatives or distributors.

LATE RESULTS

In general, late results will not be accepted after the final date.

Late results will only be accepted where there has been an error made by Randox Laboratories HQ, Randox representatives or distributors.

CORRECTED RESULTS

Laboratories may correct results only if it can be determined that the error was non-analytical and where the request for submission is within 4 weeks of the original final date. A laboratory may correct a result under the following circumstances:

- Reconstituting a sample in an incorrect volume before analysis
- Assaying and/or submitting the results for the wrong sample
- Making a transcription error - submission of an analyser print-out indicating that the analysis date was before the final date is required.

DESPATCH OF REPORTS

Results will normally be processed within 2 days of the FINAL DATE. PDF reports will be emailed the day after the results have been processed and for those registered for RIQASNet the PDF reports will be available on RIQASNet shortly after.

END OF CYCLE REPORTS

At the end of a cycle, a summary report will be issued to all participants. This includes a summary page for each parameter, an Average Absolute SDI report and a Cerificate of Acceptable performance (see below).

USE OF RIQAS REPORTS

Participants have permission to make copies of their RIQAS reports for internal use and for regulatory purposes only. RIQAS reports must not be duplicated for external use without permission from the RIQAS Scheme Co-ordinator. Under no circumstances should information on RIQAS reports be taken out of context or falsified in any way. Information regarding the format of RIQAS Reports and the monitoring of EQA performance can be found in RIQAS Explained on www.randox.com/riqas-external-quality-assessment Information regarding the calculations and scores used to evaluate participants' performance on RIQAS Reports can be found following log in to RIQASNet, in a document entitled "Evaluation of Performance".

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 regulatory authorities 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.

GENERAL DATA PROTECTION REGULATION 2018

Randox Laboratories Ltd. complies with GDPR and holds the minimum information required to maintain the contract with RIQAS customers. Contact details are required in order to effectively provide you with the RIQAS products and services. Participants are not under any obligation to provide personal information to enter into a contract with RIQAS. We recommend that business contact details are provided. All data associated with the provision of RIQAS is collated, stored and processed confidentially and securely, to avoid unlawful processing, accidental loss or damage.

CERTIFICATES OF PARTICIPATION

Complimentary certificates of participation for each RIQAS programme are made available on RIQASNet to participantsat the **end of the current cycle**, provided that **at least 50%** of results have been returned. Participants who enrol mid-cycle will be eligible for a Certificate for Participation if they have participated in at least 50% of samples available for the remainder of the cycle since enrolment. The certificate will specify the cycle, programme and the LABORATORY / HOSPITAL NAME which is detailed in the certificate section of RIQASNet. At the end of a cycle, a list of all eligible labs will be exported from RIQASNet and certificates will be created according to these details. Please ensure all certificate details are up to date in your RIQASNet account.

CERTIFICATE OF ACCEPTABLE PERFORMANCE

Participants are also provided with a Certificate of Acceptable Performance within their End-of-Cycle report. Acceptable performance is considered to be a Cycle Average Absolute SDI of less than 2. While all participants receive an end-of-cycle report, participants (including those who enrol mid-cycle) are only eligible for Certificates of Performance if they have returned more than half of the samples in a full cycle.

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, participants are invited to complete a feedback survey on RIQASNet. You may 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 raise requests or enquiries through correspondence with the local Randox Laboratories representative or by contacting RIQAS directly. Participants may appeal against the evaluation of their performance by completing a PARTICIPANT APPEALS FORM, 10770-RQ. Participants may raise a complaint in relation to the product or service provided by completing the PARTICIPANT COMPLAINTS FORM, 10772-RQ. These forms are available on RIQASNet, or on request from RIQAS.

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

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

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.

COMMUNICATION

As part of the service provided by Randox Laboratories Ltd., participants may be contacted by e-mail regarding updates and new products, in line with Randox Laboratories Ltd. privacy policy, as stated in www.randox.com.

THIS PROGRAMME IS ACCREDITED BY UKAS TO ISO/IEC 17043:2010

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Please contact RIQAS at

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Fax: +44 (0) 28 9445 4398

E-Mail mail@riqas.com

RIQAS Scheme Co-ordinator: Stephen Doherty

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RQ9129 - GLYCATED HAEMOGLOBIN ($HbA1_c$)

METHOD QUESTIONNAIRE

This programme is not suitable for use with instrument 611 - Axis-Shield Afinion

HbA1c results aligned to DCCT / NGSP (%)

CODE		METHOD
GDAER	☐	Abbott Aeroset
GDARCA	☐	Abbott Architect c (Direct Turbidimetric)
GDARC	☐	Abbott Architect c / Alinity c
GDARI	☐	Abbott Architect i / Alinity i
GDABX	☐	Abbott Axsym
GDPEN	☐	ABX Pentra
GDAMI	☐	Agappe Mispa i2
GDAMI3	☐	Agappe Mispa i3
GDACE	☐	Alfa Wasserman ACE / spACE / NExCT
GDAMS	☐	AMS Sat 450
GDANM	☐	Analyticon Micro Column
GDAEA	☐	ApexBio Eclipse A1c
GDHA	☐	Arkray/Adams/Menarini A1c HA-8000 Series
GDAPC	☐	Arkray PocketChem A1c
GDAAC	☐	Audicom AC 6000 Series
GDOL	☐	Beckman AU Instruments
GDDXC	☐	Beckman DxC600/DxC800
GDCX	☐	Beckman Synchron CX4/5/7/9
GDLX	☐	Beckman Synchron LX20/PRO
GDBAH	☐	Bioanalystic Diagnostic HbA1c
GDBK	☐	Biokit Quantex HbA1c
GDTEN	☐	Biorad D-10
GDBOH	☐	Biorad D-100
GDBRD	☐	Biorad Diamat
GDDIA	☐	Biorad Diastat
GDBI2	☐	Biorad in2it
GDMIC	☐	Biorad Micromat II
GDVA	☐	Biorad Variant I
GDVAB	☐	Biorad Variant II (Boronate Affinity)
GDVA2	☐	Biorad Variant II (ion exchange)
GDB25	☐	Biosystems A15 / A25
GDB400	☐	BioSystems BA400
GDBTS	☐	Biosystems BTS Series
GDBIO	☐	Biotecnica HbA1c Direct
GDBMA	☐	Boditech Med Inc AFIAS-6
GDBMI	☐	Boditech Med Inc *i*-CHROMA
GDCC4	☐	Ceragem Cera-Stat 4000
GDCLC	☐	Ceragem Labona Check
GDCA1	☐	Clover A1c
GDCOR	☐	Cormay Accent
GDDIH	☐	DiaSys HbA1c
GDDE	☐	Diazyme Direct Enzymatic HbA1c
GDDU3	☐	Dionex Ultimate 3000 LC system
GDDIR	☐	DIRUI
GDDMH	☐	Dr Muller HbA1c ID
GDS360	☐	Drew DS360
GDDS5	☐	Drew DS5/G15
GDGEC	☐	Gesan Chem 400
GDHBG	☐	Drew Hb-Gold
GDEQL	☐	EKF Quotient Quo-Lab A1c Test
GDQUOT	☐	EKF Quotient Quo-Test A1c Test
GDEC	☐	Erba-Chem EC-5
GDEHV	☐	Erba Hb-Vario
GDEXL	☐	Erba XL Series
GDFDE	☐	Fortress Diagnostics Electalyte-500
GDDEP	☐	Genius PA 54
GDGNS	☐	Goldsite Nephstar
GDHEC	☐	HemoCue Hb
GDHIP	☐	Hipro Latex-enhanced Turbidimetric

CODE		METHOD
GDH7	☐	Hitachi 7 series
GDH9	☐	Hitachi 9 series
GDAG	☐	HP Agilent 1100
GDHUM	☐	Human Autohumalyser
GDHDH	☐	Human Diagnostics HumaNex A1c
GDHME	☐	Human HumaMeter A1c
GDIHB	☐	Indvia Hb-one plus
GDIBQ	☐	Inter Bio-lab iQ-A1c Plus
GDMIV	☐	I.S.E. srl Mivra
GDIS	☐	i-sens A1 Care
GDIL3	☐	Ilab 300 plus
GDIL	☐	ILab 600/Monarch
GDJEB	☐	JEOL BM Test HbA1c
GDKON	☐	Konelab 20/30/60 / Thermo Indiko
GDLLD	☐	Labnovation LD-500
GDLTA	☐	LTA manual HbA1
GDMMQ	☐	Medconn MQ2000PT HPLC
GDMM	☐	Merck Microlab
GDMR	☐	Milton Roy, Spectronic
GDMIN	☐	Mindray BS200/300/400
GDMH50	☐	Mindray H50/ H50P
GDMTI	☐	MTI Diagnostics HA-1500
GDNKC	☐	Nihon Kohden Celltac Chemi
GDNYC	☐	Nycocard Reader
GDFUS	☐	Ortho Vitros 4600/5600/5.1 FS/XT 7600
GDPPC	☐	Paramedical PKL PPC Automatic Series
GDPH20	☐	Prestige H-20 Analyser
GDRXD	☐	Randox Rx HbA1c
GDRX2	☐	Randox Rx HbA1c II
GDCO3	☐	Roche Cobas 4000 / c311
GDCOB	☐	Roche Cobas 6000 / 8000
GDCO5	☐	Roche Cobas c503
GDRC53	☐	Roche Cobas c513
GDMIR	☐	Roche Cobas Mira
GDGDX	☐	Roche GDx (Boronate Affinity)
GDINT	☐	Roche Integra
GDMOP	☐	Roche Modular P / Cobas c111
GDSD	☐	SD A1c Care
GDSC2	☐	Sebia Capilarys / Minicap
GDSLH	☐	Shenzhen Lifotronic H9
GDSL	☐	Shenzhen Lifotronic HbA1c
GDA1C	☐	Siemens/Bayer A1c Now Plus
GDADV	☐	Siemens/Bayer ADVIA 1200/1650/1800/2400
GDRA	☐	Siemens/Bayer RA50
GDDD	☐	Siemens/Dade Dimension
GDDCA	☐	Siemens DCA2000 / Vantage
GDS240	☐	Spinreact Spintech 240
GDTCD	☐	Teco Diagnostics Matrix
GDTBS	☐	Tokyo Boeki / Prestige 24i
GDTOSA	☐	TOSOH AIA Series
GDTO2	☐	TOSOH A1c 2.2 Plus
GDTOS	☐	TOSOH HLC723 / G7 / G8 / GX
GDTRI	☐	Trimaris HbA1c
GDPRI	☐	Trinity Biotech Primus CLC385/PDQ/Ultra 2
GDTBT	☐	Trinity Biotech Tri-stat
GDTPR	☐	Trinity/Menarini Premier Hb9210
GDVDH	☐	Vital Diagnostics HbA1c direct
GDFLX	☐	Vitalab Flexor / Selectra
GDZVT	☐	Zivak Technologies HPLC
GDZHB	☐	Zovec Z-Hb Confirm HPLC

Other Methods - Please specify on the document

INSTRUMENT CODE ☐

REAGENT CODE ☐

RQ9129 - GLYCATED HAEMOGLOBIN ($HbA1_c$)

METHOD QUESTIONNAIRE

This programme is not suitable for use with instrument 611 - Axis-Shield Afinion

Total Hb results aligned to DCCT / NGSP (g/dl)

CODE		METHOD
GDAER	☐	Abbott Aeroset
GDARC	☐	Abbott Architect c / Alinity c
GDARI	☐	Abbott Architect i / Alinity i
GDABX	☐	Abbott Axsym
GDPEN	☐	ABX Pentra
GDAMI	☐	Agappe Mispa i2
GDACE	☐	Alfa Wasserman ACE / spACE / NExCT
GDAMS	☐	AMS Sat 450
GDHA	☐	Arkray/Adams/Menarini A1c HA-8000 Series
GDAAC	☐	Audicom AC 6000 Series
GDOL	☐	Beckman AU Instruments
GDDXC	☐	Beckman DxC600/DxC800
GDCX	☐	Beckman Synchron CX4/5/7/9
GDLX	☐	Beckman Synchron LX20/PRO
GDTEN	☐	Biorad D-10
GDBRD	☐	Biorad Diamat
GDDIA	☐	Biorad Diastat
GDMIC	☐	Biorad Micromat II
GDVA	☐	Biorad Variant I
GDVAB	☐	Biorad Variant II (Boronate Affinity)
GDVA2	☐	Biorad Variant II (ion exchange)
GDB25	☐	Biosystems A15 / A25
GDB400	☐	BioSystems BA400
GDBTS	☐	Biosystems BTS Series
GDCC4	☐	Ceragem Cera-Stat 4000
GDCOR	☐	Cormay Accent
GDDS5	☐	Drew DS5/G15
GDHBG	☐	Drew Hb-Gold
GDDIR	☐	DIRUI
GDQUOL	☐	EKF Quotient Quo-Lab A1c Test
GDQUOT	☐	EKF Quotient Quo-Test A1c Test
GDEC	☐	Erba-Chem EC-5
GDEHV	☐	Erba Hb-Vario
GDFDE	☐	Fortress Diagnostics Electalyte-500
GDGEC	☐	Gesan Chem 400
GDHEC	☐	HemoCue Hb
GDHIP	☐	Hipro Latex-enhanced Turbidimetric

CODE		METHOD
GDH7	☐	Hitachi 7 series
GDH9	☐	Hitachi 9 series
GDAG	☐	HP Agilent 1100
GDHUM	☐	Human Autohumalyser
GDIL3	☐	ILab 300 plus
GDIL	☐	ILab 600/Monarch
GDMIV	☐	I.S.E. srl Mivra
GDJEB	☐	JEOL BM Test HbA1c
GDKON	☐	Konelab 20/30/60 / Thermo Indiko
GDLLD	☐	Labnovation LD-500
GDMMQ	☐	Medconn MQ2000PT HPLC
GDMM	☐	Merck Microlab
GDMR	☐	Milton Roy, Spectronic
GDMIN	☐	Mindray BS200/300/400
GDMH50	☐	Mindray H50/H50P
GDNYC	☐	Nycocard Reader
GDFUS	☐	Ortho Vitros 4600 / 5600 / 5.1 FS
GDRXD	☐	Randox Rx Series
GDCO3	☐	Roche Cobas 4000/c311
GDCOB	☐	Roche Cobas 6000 / 8000
GDCO5	☐	Roche Cobas c503
GDRC53	☐	Roche Cobas c513
GDMIR	☐	Roche Cobas Mira
GDGDX	☐	Roche GDx (Boronate Affinity)
GDINT	☐	Roche Integra
GDMOP	☐	Roche Modular P / Cobas c111
GDSC2	☐	Sebia Capilarys / Minicap
GDADV	☐	Siemens/Bayer ADVIA 1200 / 1650 / 1800 / 2400
GDRA	☐	Siemens/Bayer RA50
GDDD	☐	Siemens/Dade Dimension
GDDCA	☐	Siemens DCA2000 / Vantage
GDTOSA	☐	TOSOH AIA Series
GDTOS	☐	TOSOH HLC723 / G7 / G8 / GX
GDPRI	☐	Trinity Biotech Primus CLC385 / PDQ / Ultra 2
GDTBT	☐	Trinity Biotech Tri-stat
GDTPR	☐	Trinity/Menarini Premier Hb9210
GDVDH	☐	Vital Diagnostics HbA1c direct
GDFLX	☐	Vitalab Flexor / Selectra

Other Methods - Please specify on the document

INSTRUMENT CODE ☐

REAGENT CODE ☐

OTHER UNITS, SPECIFY ☐

RQ9129 - GLYCATED HAEMOGLOBIN ($HbA1_c$)

METHOD QUESTIONNAIRE

This programme is not suitable for use with instrument 611 - Axis-Shield Afinion

HbA1c results aligned to IFCC (mmol/mol)

CODE		METHOD
GIAER	☐	Abbott Aeroset
GIARC	☐	Abbott Architect c / Alinity c
GIARI	☐	Abbott Architect i /Alinity i
GIPEN	☐	ABX Pentra
GIAMI	☐	Agappe Mispa i2
GIAM3	☐	Agappe Mispa i3
GIACE	☐	Alfa Wasserman ACE / spACE / NExCT
GIAMS	☐	AMS Sat 450
GIANM	☐	Analyticon Micro Column
GIHA	☐	Arkray/Adams/Menarini A1c HA-8000 Series
GIAAC	☐	Audicom AC 6000 Series
GIOL	☐	Beckman AU Instruments
GIDXC	☐	Beckman DxC600/DxC800
GICX	☐	Beckman Synchron CX 4 / 5 / 7 / 9
GILX	☐	Beckman Synchron LX20 / PRO
GIBAH	☐	Bioanalystic Diagnostic HbA1c
GIBK	☐	Biokit Quantex HbA1c
GITEN	☐	Biorad D-10
GIBOH	☐	Biorad D-100
GIBRD	☐	Biorad Diamat
GIDIA	☐	Biorad Diastat
GIBI2	☐	Biorad in2it
GIMIC	☐	Biorad Micromat II
GIVA	☐	Biorad Variant I
GIVA2	☐	Biorad Variant II
GIB25	☐	Biosystems A15 / A25
GIB400	☐	BioSystems BA400
GIBTS	☐	Biosystems BTS Series
GIBIO	☐	Biotecnica HbA1c Direct
GICC4	☐	Ceragem Cera-Stat 4000
GICLC	☐	Ceragem Labona Check
GICA1	☐	Clover A1c
GIDIH	☐	DiaSys HbA1c
GIDE	☐	Diazyme Direct Enzymatic HbA1c
GIDU3	☐	Dionex Ultimate 3000 LC system
GIDIR	☐	DIRUI
GIDMH	☐	Dr Muller HbA1c ID
GIDS360	☐	Drew DS360
GIDS5	☐	Drew Ds5/G15
GIHBG	☐	Drew Hb-Gold
GIEQL	☐	EKF Quotient Quo-Lab A1c Test
GIQUOT	☐	EKF Quotient Quo-Test A1c Test
GIEC	☐	Erba-Chem EC-5
GIEHV	☐	Erba Hb-Vario
GIEXL	☐	Erba XL Series
GIFDE	☐	Fortress Diagnostics Electalyte-500
GIGEC	☐	Gesan Chem 400
GIGNS	☐	Goldsite Nephstar
GIHEC	☐	HemoCue Hb
GIHIP	☐	Hipro Latex-enhanced Turbidimetric

CODE		METHOD
GIH7	☐	Hitachi 7 series
GIH9	☐	Hitachi 9 series
GIAG	☐	HP Agilent 1100
GIHUM	☐	Human Autohumalyser
GIHDH	☐	Human Diagnostics HumaNex A1c
GIHME	☐	Human HumaMeter A1c
GIIL	☐	ILab 600/Monarch
GIIHB	☐	Indvia Hb-one plus
GIIBQ	☐	Inter Bio-lab iQ-A1c Plus
GIJEB	☐	JEOL BM Test HbA1c
GIKON	☐	Konelab 20/30/60 / Thermo Indiko
GILLD	☐	Labnovation LD-500
GILTA	☐	LTA manual HbA1
GIMMQ	☐	Medconn MQ2000PT HPLC
GIMM	☐	Merck Microlab
GIMR	☐	Milton Roy, Spectronic
GIMIN	☐	Mindray BS200/300/400
GIMH50	☐	Mindray H50/ H50P
GINYC	☐	Nycocard Reader
GIFUS	☐	Ortho Vitros 4600/5600/5.1 FS/XT 7600
GIPH20	☐	Prestige H-20 Analyser
GIRXD	☐	Randox Rx HbA1c
GIRX2	☐	Randox Rx HbA1c II
GICO3	☐	Roche Cobas 4000 / c311
GICOB	☐	Roche Cobas 6000 / 8000
GICO5	☐	Roche Cobas c503
GIRC53	☐	Roche Cobas c513
GIMIR	☐	Roche Cobas Mira
GIGDX	☐	Roche GDx (Boronate Affinity)
GIINT	☐	Roche Integra
GIMOP	☐	Roche Modular P / Cobas c111
GISC2	☐	Sebia Capilarys / Minicap
GISLH	☐	Shenzhen Lifotronic H9
GISL	☐	Shenzhen Lifotronic HbA1c
GIA1C	☐	Siemens/Bayer A1c Now Plus
GIADV	☐	Siemens/Bayer ADVIA 1200/1650/1800/2400
GIRA	☐	Siemens/Bayer RA50
GIDD	☐	Siemens/Dade Dimension
GIDCA	☐	Siemens DCA2000 / Vantage
GITCD	☐	Teco Diagnostics Matrix
GITBS	☐	Tokyo Boeki / Prestige 24i
GITOSA	☐	TOSOH AIA Series
GITOS	☐	TOSOH HLC723 / G7 / G8 / GX
GIPRI	☐	Trinity Biotech Primus CLC385 / PDQ / Ultra 2
GITBT	☐	Trinity Biotech Tri-stat
GITPR	☐	Trinity/Menarini Premier Hb9210
GIFLX	☐	Vitalab Flexor / Selectra
GIZVT	☐	Zivak Technologies HPLC

Other Methods - Please specify on the document

INSTRUMENT CODE ☐

REAGENT CODE ☐

OTHER UNITS, SPECIFY ☐

RQ9129 - GLYCATED HAEMOGLOBIN ($HbA1_c$)

METHOD QUESTIONNAIRE

This programme is not suitable for use with instrument 611 - Axis-Shield Afinion

Total Hb results aligned to IFCC (g/dl)

CODE		METHOD
GIAER	☐	Abbott Aeroset
GIARC	☐	Abbott Architect c / Alinity c
GIARI	☐	Abbott Architect i / Alinity i
GIPEN	☐	ABX Pentra
GIACE	☐	Alfa Wasserman ACE / spACE / NExCT
GIAMS	☐	AMS Sat 450
GIHA	☐	Arkray/Adams/Menarini A1c HA-8000 Series
GIAAC	☐	Audicom AC 6000 Series
GIOL	☐	Beckman AU Instruments
GIDXC	☐	Beckman DxC600/DxC800
GICX	☐	Beckman Synchron CX 4 / 5 / 7 / 9
GILX	☐	Beckman Synchron LX20 / PRO
GITEN	☐	Biorad D-10
GIBRD	☐	Biorad Diamat
GIDIA	☐	Biorad Diastat
GIMIC	☐	Biorad Micromat II
GIVA	☐	Biorad Variant I
GIVA2	☐	Biorad Variant II
GIB25	☐	Biosystems A15 / A25
GIB400	☐	BioSystems BA400
GIBTS	☐	Biosystems BTS Series
GICC4	☐	Ceragem Cera-Stat 4000
GICOR	☐	Cormay Accent
GIDIR	☐	DIRUI
GIDS5	☐	Drew Ds5/G15
GIHBG	☐	Drew Hb-Gold
GIQUOL	☐	EKF Quotient Quo-Lab A1c Test
GIQUOT	☐	EKF Quotient Quo-Test A1c Test
GIEC	☐	Erba-Chem EC-5
GIEHV	☐	Erba Hb-Vario
GIFDE	☐	Fortress Diagnostics Electalyte-500
GIGEC	☐	Gesan Chem 400
GIHEC	☐	HemoCue Hb
GIHIP	☐	Hipro Latex-enhanced Turbidimetric
GIH7	☐	Hitachi 7 series
GIH9	☐	Hitachi 9 series
GIAG	☐	HP Agilent 1100
GIHUM	☐	Human Autohumalyser
GIIL3	☐	ILab 300 Plus
GIIL	☐	ILab 600 / 650 / Monarch
GIKON	☐	Konelab 20/30/60 / Thermo Indiko
GILLD	☐	Labnovation LD-500
GIMMQ	☐	Medconn MQ2000PT HPLC
GIMM	☐	Merck Microlab
GIMR	☐	Milton Roy, Spectronic
GIMIN	☐	Mindray BS200 / 300 / 400
GIMH50	☐	Mindray H50/H50P
GINYC	☐	Nycocard Reader
GIFUS	☐	Ortho Vitros 4600 / 5600 / 5.1 FS
GIRXD	☐	Randox Rx Series
GICO3	☐	Roche Cobas 4000 / c311
GICOB	☐	Roche Cobas 6000 / 8000
GICO5	☐	Roche Cobas c503
GIRC53	☐	Roche Cobas c513
GIMIR	☐	Roche Cobas Mira
GIGDX	☐	Roche GDx (Boronate Affinity)
GIINT	☐	Roche Integra
GIMOP	☐	Roche Modular P / Cobas c111
GISC2	☐	Sebia Capilarys / Minicap
GIADV	☐	Siemens/Bayer ADVIA 1200/1650/1800/2400
GIRA	☐	Siemens/Bayer RA50
GIDD	☐	Siemens/Dade Dimension
GIDCA	☐	Siemens DCA2000 / Vantage
GITBS	☐	Tokyo Boeki / Prestige 24i
GITOSA	☐	TOSOH AIA Series
GITOS	☐	TOSOH HLC723 / G7 / G8 / GX
GIPRI	☐	Trinity Biotech Primus CLC385 / PDQ / Ultra 2
GITBT	☐	Trinity Biotech Tri-stat
GITPR	☐	Trinity/Menarini Premier Hb9210
GIFLX	☐	Vitalab Flexor / Selectra
GIFLX	☐	Vitalab Flexor / Selectra

Other Methods - Please specify on the document

INSTRUMENT CODE

REAGENT CODE

OTHER UNITS, SPECIFY

RQ9129 - GLYCATED HAEMOGLOBIN ($HbA1_c$)

METHOD QUESTIONNAIRE

This programme is not suitable for use with instrument 611 - Axis-Shield Afinion

Non-aligned HbA1c results (%)

CODE		METHOD
GNAER	☐	Abbott Aeroset
GNARC	☐	Abbott Architect c Systems
GNARI	☐	Abbott Architect i Systems
GNABX	☐	Abbott Axsym
GNPEN	☐	ABX Pentra
GNAMI	☐	Agappe Mispa i2
GNACE	☐	Alfa Wasserman ACE / spACE / NExCT
GNAMS	☐	AMS Sat 450
GNANM	☐	Analyticon Micro Column
GNHA	☐	Arkray/Adams/Menarini A1c HA-8000 Series
GNAAC	☐	Audicom AC 6000 Series
GNOL	☐	Beckman AU Instruments
GNCX	☐	Beckman Synchron CX 4 / 5 / 7 / 9
GNLX	☐	Beckman Synchron LX20 / PRO
GNBK	☐	Biokit Quantex HbA1c
GNTEN	☐	Biorad D-10
GNBOH	☐	Biorad D-100
GNBRD	☐	Biorad Diamat
GNDIA	☐	Biorad Diastat
GNMIC	☐	Biorad Micromat II
GNVA	☐	Biorad Variant I
GNVA2	☐	Biorad Variant II
GNB25	☐	Biosystems A15 / A25
GNB400	☐	BioSystems BA400
GNBTS	☐	Biosystems BTS Series
GNCLC	☐	Ceragem Labona Check
GNCA1	☐	Clover A1c
GNCBS	☐	Crest Biosystems Kit
GNDE	☐	Diazyme Direct Enzymatic HbA1c
GNDU3	☐	Dionex Ultimate 3000 LC system
GNDIR	☐	DIRUI
GNDMH	☐	Dr Muller HbA1c ID
GNDS5	☐	Drew DS5 / G15
GNHBG	☐	Drew Hb-Gold
GNEC	☐	Erba-Chem EC5
GNQUOL	☐	EKF Quotient Quo-Lab A1c Test
GNQUOT	☐	EKF Quotient Quo-Test A1c Test
GNEXL	☐	Erba XL Series
GNFDE	☐	Fortress Diagnostics Electalyte-500
GNGEC	☐	Gesan Chem 400
GNGET	☐	Getein HbA1c
GNGNS	☐	Goldsite Nephstar
GNHEC	☐	HemoCue Hb
GNHIP	☐	Hipro Latex-enhanced Turbidimetric
GNH7	☐	Hitachi 7 series
GNH9	☐	Hitachi 9 series

CODE		METHOD
GNAG	☐	HP Agilent 1100
GNHUM	☐	Human Autohumalyser
GNHMT	☐	Human Manual HbA1c Test
GNIL	☐	ILab 600/Monarch
GNJEB	☐	JEOL BM Test HbA1c
GNKON	☐	Konelab 20/30/60 / Thermo Indiko
GNLLD	☐	Labnovation LD-500
GNLTA	☐	LTA manual HbA1
GNMMQ	☐	Medconn MQ2000PT HPLC
GNMM	☐	Merck Microlab
GNMR	☐	Milton Roy, Spectronic
GNMIN	☐	Mindray BS200 / 300 / 400
GNNYC	☐	Nycocard Reader
GNFUS	☐	Ortho Vitros 4600/5600/5.1 FS/XT 7600
GNRXD	☐	Randox Rx Series
GNCO3	☐	Roche Cobas 4000 / c311
GNCOB	☐	Roche Cobas 6000 / 8000
GNRC53	☐	Roche Cobas c513
GNMIR	☐	Roche Cobas Mira
GNGDX	☐	Roche GDx (Boronate Affinity)
GNINT	☐	Roche Integra
GNMOP	☐	Roche Modular P / Cobas c111
GNSC2	☐	Sebia Capilarys / Minicap
GNSLH	☐	Shenzhen Lifotronic H9
GNSL	☐	Shenzhen Lifotronic HbA1c
GNSPH	☐	Shimadzu Prominence HPLC
GNA1C	☐	Siemens/Bayer A1C Now Plus
GNADV	☐	Siemens/Bayer ADVIA 1200/1650/1800/2400
GNEXP	☐	Siemens/Bayer Express Plus
GNRA	☐	Siemens/Bayer RA50
GNDD	☐	Siemens/Dade Dimension
GNDCA	☐	Siemens DCA2000 / Vantage
GNSPR	☐	Spinreact
GNSB	☐	Stanbio
GNTCD	☐	Teco Diagnostics Matrix
GNTBS	☐	Tokyo Boeki / Prestige 24i
GNTOSA	☐	TOSOH AIA Series
GNTOS	☐	TOSOH HLC723 / G7 / G8 / GX
GNPRI	☐	Trinity Biotech Primus CLC385 / PDQ / Ultra 2
GNTBT	☐	Trinity Biotech Tri-stat
GNTPR	☐	Trinity/Menarini Premier Hb9210
GNFLX	☐	Vitalab Flexor / Selectra
GNZVT	☐	Zivak Technologies HPLC

Other Methods - Please specify on the document

INSTRUMENT CODE ☐

REAGENT CODE ☐

RQ9129 - GLYCATED HAEMOGLOBIN ($HbA1_c$)

METHOD QUESTIONNAIRE

This programme is not suitable for use with instrument 611 - Axis-Shield Afinion

Non-aligned Total Hb results (g/dl)

CODE		METHOD
GNAER	☐	Abbott Aeroset
GNARC	☐	Abbott Architect c Systems
GNARI	☐	Abbott Architect i Systems
GNPEN	☐	ABX Pentra
GNACE	☐	Alfa Wasserman ACE / spACE / NExCT
GNAMS	☐	AMS Sat 450
GNHA	☐	Arkray/Adams/Menarini A1c HA-8000 Series
GNAAC	☐	Audicom AC 6000 Series
GNOL	☐	Beckman AU Instruments
GNCX	☐	Beckman Synchron CX4 / 5 / 7 / 9
GNLX	☐	Beckman Synchron LX20 / PRO
GNTEN	☐	Biorad D-10
GNBRD	☐	Biorad Diamat
GNDIA	☐	Biorad Diastat
GNMIC	☐	Biorad Micromat II
GNVA	☐	Biorad Variant I
GNVA2	☐	Biorad Variant II
GNB25	☐	Biosystems A15 / A25
GNB400	☐	BioSystems BA400
GNBTS	☐	Biosystems BTS Series
GNCOR	☐	Cormay Accent
GNCBS	☐	Crest Biosystems kit
GNDIR	☐	DIRUI
GNDS5	☐	Drew DS5 / G15
GNHBG	☐	Drew Hb-Gold
GNQUOL	☐	EKF Quotient Quo-Lab A1c Test
GNQUOT	☐	EKF Quotient Quo-Test A1c Test
GNEC	☐	Erba-Chem EC5
GNFDE	☐	Fortress Diagnostics Electalyte-500
GNGEC	☐	Gesan Chem 400
GNHEC	☐	HemoCue Hb
GNHIP	☐	Hipro Latex-enhanced Turbidimetric
GNH7	☐	Hitachi 7 series
GNH9	☐	Hitachi 9 series

CODE		METHOD
GNAG	☐	HP Agilent 1100
GNHUM	☐	Human Autohumalyser
GNIL3	☐	ILab 300 plus
GNIL	☐	ILab 600 / 650 / Monarch
GNKON	☐	Konelab 20/30/60 / Thermo Indiko
GNLLD	☐	Labnovation LD-500
GNMMQ	☐	Medconn MQ2000PT HPLC
GNMM	☐	Merck Microlab
GNMR	☐	Milton Roy, Spectronic
GNMIN	☐	Mindray BS200 / 300 / 400
GNNYC	☐	Nycocard Reader
GNFUS	☐	Ortho Vitros 4600 / 5600 / 5.1 FS
GNRXD	☐	Randox Rx Series
GNCOB	☐	Roche Cobas 6000 / 8000
GNRC53	☐	Roche Cobas c513
GNMIR	☐	Roche Cobas Mira
GNGDX	☐	Roche GDx (Boronate Affinity)
GNINT	☐	Roche Integra
GNMOP	☐	Roche Modular P / Cobas c111
GNSC2	☐	Sebia Capilarys / Minicap
GNSPH	☐	Shimadzu Prominence HPLC
GNDCA	☐	Siemens DCA2000 / Vantage
GNADV	☐	Siemens/Bayer ADVIA 1200 / 1650 / 1800 / 2400
GNEXP	☐	Siemens/Bayer Express Plus
GNRA	☐	Siemens/Bayer RA50
GNDD	☐	Siemens/Dade Dimension
GNSPR	☐	Spinreact
GNTBS	☐	Tokyo Boeki/Prestige 24i
GNTOSA	☐	TOSOH AIA Series
GNTOS	☐	TOSOH HLC723 / G7 / G8 / GX
GNPRI	☐	Trinity Biotech Primus CLC385 / PDQ / Ultra 2
GNTBT	☐	Trinity Biotech Tri-stat
GNTPR	☐	Trinity/Menarini Premier Hb9210
GNFLX	☐	Vitalab Flexor / Selectra

Other Methods - Please specify on the document

INSTRUMENT CODE ☐

REAGENT CODE ☐

OTHER UNITS, SPECIFY ☐