RIQAS POINT OF CARE

RANDOX INTERNATIONAL QUALITY ASSESSMENT SCHEME

ENROLMENT DOCUMENT
WHOLE BLOOD
PROGRAMME
RQ9181

This document must be completed and returned to RIQAS

REGISTRATION INSTRUCTIONS & RIQAS POINT OF CARE POLICIES

CRITERIA FOR PARTICIPATION

This programme is available to any laboratory, pharmacy, health care provider running the assays listed in this document. Quantitative results will be accepted on this programme.

INTRODUCTION

The RIQAS Point of Care policy document is designed to allow you to register for this RIQAS Programme and to inform you of RIQAS protocols and policies. These are reviewed and updated every month, as indicated by the issue date at the bottom of every page.
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.

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.

LABORATORY REFERENCE NUMBER

On receipt of an enrolment document, each participant is assigned a **laboratory ID number** which is unique to your site. If you are a previous customer please ensure your site name is the same as on previous enrolment documents. On initial registration you will be sent RIQAS literature, which will enable you to understand the RIQAS process and interpret your reports. Pkease quote your site name on all correspondence with RIQAS.

GROUP REPORTS

It is possible to enrol multiple instruments within your laboratory, clearly identify each instrument on the enrolment document. A complementary instrument group report is then supplied if you have more than one instrument registered.
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 provided the group box is completed on the enrolment document.

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.

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.

PRIMARY CONTACT DETAILS

It is important to state the full address details of the contact person who will receive all correspondence during the cycle. This will be the administrator of your site. 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.

QC PLATFORM

The Randox QC platform is a web-based online method for result entry / additions/updates of instruments and parameters / viewing of released reports. To access Randox QC platform go to qc.randox.com. Internet access and login details are required for Randox QC platform. Your initial login information will be supplied by RIQAS. When you are logging in for the first time you will be required to create your Randox QC platform password. If you forget your password please follow the 'Forgotten Password' link. Your login information will be based on the email address you supply on your enrolment document. An email notification of the availability of the report will be sent to this address.

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 most recent RIQAS policies 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.

REGISTRATION OF ASSAY DETAILS

Labs can register their instruments and tests using the QC platform or can complete the 'Instrument & Test Registration' section of the enrolment document. Labs should tick the appropriate box under the 'Registration of Assay Details' section of the enrolment document.

Once a participant has registered they will receive an email containing login information for the QC platform. Once you have successfully logged in to the QC platform you can select setup and you will see your site details and in instruments that you have registered.
If you have opted to add parameter/assay details using the QC platofrm, please do so as soon as possible (see below.)

ONCE COMPLETED, THE ENROLMENT DOCUMENT SHOULD BE SENT TO RIQAS **FOR REGISTRATION.**

UPDATING ASSAY DETAILS

It is possible to change your instrumentclassification during a cycle.

Instrument Changes via QC Platform: These can be made in the Instrument Setup section of the platform. A list of your registered instruments will appear on screen. To change the details double click on the line you wish to change. Enter any new details. Save the changes and submit them to RIQAS. To add a new instrument click the 'add new' button at the bottom of the page. Enter all details and save the changes. Changes will be instantaneously updated on the QC platform.

ADDITION OF PARAMETERS / ASSAY DETAILS

Adding Parameters via QC Platform: Parameters can be added using the Panel Setup section. A list of your registered panels will appear on screen. Click on the arrow next to the panel you wish to update. Double click on the instrument you wish to add the parameters to. A list of parameters available on this panel will show. Click the radar button next to the parameter you wish to add, ensure it is blue. Save the changes and submit them to RIQAS. Additions will be available on the QC Platform instaneously.

Parameter can be deactivate on the QC Platform: As above, on the page with the parameter list click on the radar button next to parameter you wish to remove and ensure it is grey.

ORDERING RIQAS PRODUCTS

Please ensure when registering for your first cycle the order 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 to receive the next available sample in the cycle. 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 the QC Platform please access your account and download the relevant Instructions For Use (IFU) document for the programme and cycle purchased. The IFU includes material characteristics, preparation, stability, storage and safety information.

On receipt of your RIQAS kit, please check that:

a) it is the product you ordered

b) 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 the QC Platform 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 **24:00 GMT on the FINAL DATE**, as indicated in the IFU. Results are submitted via the QC Platform, which can be accessed once you have received log in details via email.

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”. 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 the QC Platform.

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:

- 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 1 day of the FINAL DATE. Reports will be available on the QC Platform the same day the results are processed.

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.

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 REGISTRATION

Complimentary certificates of registration for each RIQAS programme can be provided upon request.

CERTIFICATE OF ACCEPTABLE PERFORMANCE

Participants are also provided with a Certificate of Acceptable Performancet. Acceptable performance is considered to be a Cycle Average Absolute SDI of

PARTICIPANT FEEDBACK, COMPLAINTS & APPEALS

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 request from RIQAS.

SUB-CONTRACTING

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.

OUR COMPETENCE AS A PROFICIENCY TESTING PROVIDER

On request, RIQAS is willing to co-operate with participants seeking evidence of our competence as a proficiency testing provider or information on the design and implementation of RIQAS Programmes.

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.

Please contact RIQAS at
Tel: +44 (0) 28 9445 4399
Fax: +44 (0) 28 9445 4398
E-Mail mail@riqas.com
RIQAS Scheme Co-ordinator: Sally Picton
RANDOX LABORATORIES LTD., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom

RIQAS Point of Care

WHOLE BLOOD

RQ9181

Group Name:
(e.g. "AnyWhere" Council; "Big" Pharmacies)
(Please note: By completing this box you consent to your data being shared with the co-ordinator assigned to this group.)

Site name:
(e.g. "AnyTown" Surgery; "Town" Pharmacy)

Contact Name:
(to whom the EQA sample is sent monthly)

Delivery Address:
(where the EQA sample is sent monthly)

Postcode:

Email Address 1:
(Primary Contact email for RIQAS POC website)

Email Address 2:

Email Address 3:

Enrolment Date:

Purchase Order Number:

Customer Declaration: By submitting this enrolment document to RIQAS, either directly or via my local Randox representative, I, (the customer of RIQAS) confirm that:

1) I have read and understood the RIQAS Point of Care policies stated in the policies document.
2) I understand that the submission of this enrolment document to RIQAS marks the beginning of an on-going agreement, and I will be automatically enrolled in subsequent cycles of this programme until RIQAS receives written confirmation of my cancellation.
3) I understand that I must inform RIQAS of any changes to my contact details, assay details or contract status
4) I authorise Randox Laboratories Ltd. to send communication related to the products and service provided to the e-mail or postal addresses stated on this document
5) I understand that I am permitted to request disclosure of, change or erase personal details held by Randox Laboratories Ltd. at any time

Addition of Instruments and Tests

Please select one of the following options

☐ **I wish to add my own assay details via the QC Platform once I have received my username and password from RIQAS** (You do not need to complete the section overleaf)

☐ **I wish to inform RIQAS of my assay details using this enrolment document** (please complete the section overleaf)

SITE NAME: _____

RIQAS POINT OF CARE WHOLE BLOOD PROGRAMME

REGISTRATION OF ASSAY DETAILS

ONLY COMPLETE THIS SECTION IF YOU DO NOT INTEND TO REGISTER YOUR INSTRUMENTS ONLINE

Please indicate your requirements by ✓ or by writing in the boxes below.

Instrument & Test Registration					
INSTRUMENT MANUFACTURER	INSTRUMENT MODEL	INSTRUMENT SERIAL NUMBER	LIPIDS	HbA1c	CRP

Please fill in as much information as possible on this form. Make sure that your delivery and email address details are correct and return your form to your sales representative. If you have a problem when filling in this form, please contact your sales representative or RIQAS_POC@randox.com.

Please note: Returning an incomplete form may result in your registration to RIQAS being delayed.