# REGISTRATION INSTRUCTIONS & RIQAS POLICIES

## CRITERIA FOR PARTICIPATION

This programme is available to any laboratory running the Ammonia Ethanol assays listed in this document. 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/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/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 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 , reagent , and the units that you use in your laboratory if they are different from the RIQAS standard units. If a method is not available for your assay, please state the details of your method clearly in the section at the end of the enrolment document.

**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 **Instrument number** which is assigned for each new instrument 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. Please quote this number on all correspondence with RIQAS.

**B. GROUP REPORTS AND MULTIPLE REGISTRATIONS**

Assessment of the same parameters on multiple systems - It is possible to enrol multiple instruments within your laboratory, up to five instruments per programme (volume permitting) can be added at no extra cost for comparative performance assessment. If you wish for RIQAS to add additional instruments you must 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 instrument 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/Coordinator report for each sample can be made available on receipt of a completed authorisation form from each registered laboratory. Please contact RIQAS for a copy of the official inter-laboratory/Coordinator authorisation form.

**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. 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.

**E. RIQAScom**

RIQAS.com is an online method for result entry / method changes and additions of parameters / viewing of reports. To access RIQAS.com go to https://riqas.randox.com. Internet access and login details are required for RIQAS.com. Your initial login information and password will be supplied by RIQAS. Once you have logged in for the first time you will be required to review and accept the end user licience agreement before gaining access to the site. You are also required to change your RIQAS.com password. If you forget your password please follow the 'Forgot Password' link.

**F. PDF REPORTS**

Reports can viewed online.

The report (including its content, structure, layout, design, methodology, templates, and presentation) is protected by copyright and other intellectual property rights. No part of the report may be copied, reproduced, republished, adapted, stored, transmitted, or distributed in any form without the prior written consent of Randox Laboratories, except for the recipient's internal use only.

**G. SUMMARY CSV FILES**

Labs have access to a csv file through the 'Viewing Quantitative Results' screen on RIQAS.com 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, SDPA and z-score. Also the PERFORMANCE column will show * in place of the red triangle usually shown on the summary page of your routine report. CSV files are also available for Instrument and Inter-Laboratory group reports through Report generation screens.

**H. 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 erasure 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.

**I. REGISTRATION OF ASSAY DETAILS**

Labs can register their assay details using RIQAScom 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 methods from this questionnaire and the Instrument/Reagent Supplier Book.

Once a participant has registered they will receive an email containing their RIQAS.com login information. Once you have successfully logged in to RIQAS.com and accepted the end user licence agreenement you will see your laboratory details. If you have opted to add parameters/assay details using RIQAS.com, please do so as soon as possible (see below).

If no Method 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 RIQAS.com. This is available in the help section on RIQAS.com.

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

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

**J. ADDING NEW ASSAY DETAILS/QA TEST**

It is possible to change your unit, instrument or reagent classification during a cycle. However, it is not possible to back date assay changes.

Method Changes via RIQAS.com: These can be made in the Assay configuration and QA Test configuration section of RIQAS.com. A list of your registered Programmes will appear on screen. Select the Programme for which you would like to change the assay details or set up a new QA test. A current list of assay details will appear, click on the appropriate parameter. To make changes to an exsisting Assays Unit or Reagent supplier, click the penicil icon and select the appropriate option from the dropdowns provided. To add a new assay select the '+' icon and enter details. Save the change. Changes will be instantaneously updated on RIQAS.com

**K. ADDITION OF PARAMETERS / ASSAY DETAILS**

Adding Parameters via RIQAS.com: Parameters can be added using the Assay configuration screen. A list of your registered Programmes will appear on screen. Select the Programme for which you would like to add the assay details. Select the '+' icon to Add a new parameter. A list of Programme parameters will appear in the drop down. Select the parameter you wish to add, include a method, reagent supplier, unit and temperature if appropriate. Save the changes. As above, additions will be available instantaneously.

## 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 RIQAS.com 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 correct number of samples are present as indicated on the IFU
c) 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 RIQAS.com 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 **23:00 GMT on the FINAL DATE**, as indicated in the IFU. Results are submitted via RIQAS.com, 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” 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 RIQAS.com.

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

Reports will be available on RIQAS.com within 72 hours of the FINAL DATE. Participants will receive an email notifying them when a report has been released.

## 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 (see Section F under Enrolment Documents. 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 the RIQAS Brochure on www.randox.com/external-quality-assessment Information regarding the calculations and scores used to evaluate participants' performance on RIQAS Reports can be found following log in to RIQAS.com, 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 & UK DATA PROTECTION ACT 2018

Randox Laboratories Ltd. complies with GDPR and the UK Data Protection Act 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 are available for Participants to create on RIQAS.com at any time, provided they have returned at least 1 result. Participants who enrol mid-cycle will be eligible for a Certificate for registration if they have participated in at least 1 sample return. Labs can enter in laboratory details for the certificate on 3 lines made available on the certificate Registration screen. Once a certificate has been created for a cycle, the informationon the certificate for that cycle can no longer be changed.

## CERTIFICATE OF ACCEPTABLE PERFORMANCE

Participants are also able to generate a Certificate of Performance via the Performance certificate sceen at any time and these will also still be available within the 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, COMPLAINTS & APPEALS

In order to ensure that RIQAS provides an appropriate and satisfying service, participants are invited to complete a feedback survey on RIQAS.com. You may contact RIQAS 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 RIQAS.com, or 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.

This programme is accredited by UKAS TO ISO/IEC 17043:2023 via Fixed Scope

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

UKAS PROFICIENCY TESTING
0010

# RIQAS

## RQ9168 - CEREBROSPINAL FLUID (CSF) PROGRAMME

### Method questionnaire

### Albumin, mg/l

**METHOD**

- ☐ Bromocresol Green (BCG)
- ☐ Bromocresol Purple (BCP)
- ☐ Nephelometric Assays
- ☐ Pyrogallol Red
- ☐ Turbidimetric Assays
- ☐ Vitros Microslide Systems
  Vitros Slide Generation Number ☐☐
- ☐ Other Dry Chemistry

Other methods, please specify on enrolment document

| | |
|---|---|
| INSTRUMENT | |
| REAGENT | |
| UNITS | |

### CHLORIDE, mmol/l

**METHOD**

- ☐ Colorimetric
- ☐ Coulometric
- ☐ Ion Selective Electrode, direct
- ☐ Ion Selective Electrode, indirect
- ☐ Titrimetric
- ☐ Ortho Vitros Microslide Systems
  Vitros Slide Generation Number ☐☐
- ☐ Other Dry Chemistry

Other methods, please specify on enrolment document

| | |
|---|---|
| INSTRUMENT | |
| REAGENT | |
| UNITS | |

### GLUCOSE, mmol/l

**METHOD**

- ☐ Glucose dehydrogenase
- ☐ Glucose oxidase
- ☐ GOD/02-Beckman method
- ☐ Hexokinase
- ☐ Oxygen electrode
- ☐ Ortho Vitros Microslide Systems
  Vitros Slide Generation Number ☐☐
- ☐ Other Dry Chemistry

Other methods, please specify on enrolment document

| | |
|---|---|
| INSTRUMENT | |
| REAGENT | |
| UNITS | |

### Immunoglobulin G, mg/l

**METHOD**

- ☐ Radial Immunodiffusion Assays
- ☐ Nephelometric Assays
- ☐ Turbidimetric Assays
- ☐ Ortho Vitros Microslide Systems
  Vitros Slide Generation Number ☐☐

Other methods, please specify on enrolment document

| | |
|---|---|
| INSTRUMENT | |
| REAGENT | |
| UNITS | |

### LACTATE mmol//l

**METHOD**

- ☐ Abbott Alinity LAC 2
- ☐ Abbott Architect LAC 2
- ☐ Colorimetric - Lactate oxidase
- ☐ Enzymatic Electrode
- ☐ Ion Selective Electrode
- ☐ Other Dry Chemistry
- ☐ UV - LDH
- ☐ Ortho Vitros MicroSlide Systems
  Vitros Slide Generation Number ☐☐

Other methods, please specify on enrolment document

| | |
|---|---|
| INSTRUMENT | |
| REAGENT | |
| UNITS | |

### PROTEIN, TOTAL, g/l

**METHOD**

# RIQAS

## RQ9168 - CEREBROSPINAL FLUID (CSF) PROGRAMME

### Method questionnaire

- [ ] Biuret reaction - direct
- [ ] Biuret reaction with precipitation
- [ ] Coomassie blue - direct
- [ ] Coomassie blue with precipitation
- [ ] Nephelometric
- [ ] Ponceau S with precipitation
- [ ] Pyrogallol Red
- [ ] Refractometry
- [ ] Siemens UCFP Reagent
- [ ] Sulphosalicylic acid
- [ ] Turbidimetry
- [ ] Vitros Microslide Systems
  Vitros Slide Generation Number [ ][ ]

Other methods, please specify on enrolment document

| | |
|---|---|
| INSTRUMENT | |
| REAGENT | |
| UNITS | |

### SODIUM, mmol/l

**METHOD**

- [ ] Chromolyte
- [ ] Colorimetric
- [ ] Enzymatic
- [ ] Flame photometry
- [ ] Ion Selective Electrode method - direct
- [ ] Ion Selective Electrode method - indirect
- [ ] Optical Fluorescence
- [ ] Ortho Vitros Microslide Systems
  Vitros Slide Generation Number [ ][ ]
- [ ] Other Dry Chemistry

Other methods, please specify on enrolment document

| | |
|---|---|
| INSTRUMENT | |
| REAGENT | |
| UNITS | |