

RIQAS

RANDOX INTERNATIONAL QUALITY ASSESSMENT SCHEME

**METHOD QUESTIONNAIRE
CYFRA 21-1 PROGRAMME
(CYTOKERATIN 19)
RQ9175**

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 the 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.

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 RIQAS website (www.riqas.com). 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.

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 on 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 and routine reports during the cycle. This is the address to which reports will be posted if you do not select an electronic correspondence method. 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. If you wish to use RIQASNet 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.

G. 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.

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. DECLARATION

The declaration indicates that you have read and understood the RIQAS policies in the most recent method questionnaire associated with the programme. The submission of the enrolment document to RIQAS, either directly or via your local Randox representative, represents your agreement for RIQAS to proceed with your registration, based on your completed enrolment document. 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.

Participants who do not wish to use RIQASNet at all 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.

Participants using RIQASNet will receive an email containing their 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.

Participants who use RIQASNet: Method changes. 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.

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.

L. ADDITION OF PARAMETERS / ASSAY DETAILS

Participants who use RIQASNet: Addition of Parameters. 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 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 ask your local Randox representative to check availability before

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:

- it is the product you ordered
- the kit contains detailed Instructions For Use (IFU), including material characteristics, preparation, stability, storage and safety
- the correct number of samples are present as indicated on the IFU
- 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. We recommend using RIQASNet to return results. 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. 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. Printed reports usually take a further 1-3 days to print and despatch.

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 Certificate 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.

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 participants at 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, 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 RIQASNet, 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 HAS NOT BEEN ACCREDITED
TO ISO / IEC 17043:2010

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: Stephen Doherty

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RQ9175 - CYFRA 21-1 PROGRAMME

METHOD QUESTIONNAIRE

CYFRA 21-1 (Cytokeratin 19) ng/ml

CODE	METHOD
CYARC	<input type="checkbox"/> Abbott Architect
CYAUT	<input type="checkbox"/> Autobio Cyfra 21-1
CYCIS	<input type="checkbox"/> CISBio CYFRA 21-1 IRMA
CYDEE	<input type="checkbox"/> Demeditec ELISA
CYLIA	<input type="checkbox"/> Diasorin Liaison BRAHMS
CYLIX	<input type="checkbox"/> Diasorin Liaison XL BRAHMS
CYDRG	<input type="checkbox"/> DRG ELISA
CYFUJ	<input type="checkbox"/> Fujirebio ELISA
CYFJL	<input type="checkbox"/> Fujirebio Lumipulse G Series
CYIMI	<input type="checkbox"/> Immunotech IRMA
CYMC2	<input type="checkbox"/> Mindray CL Series
CYEYS	<input type="checkbox"/> Roche Elecsys/Cobas/Modular systems
CYSNM	<input type="checkbox"/> SNIBE Maglumi Analysers

Other methods please specify on enrolment document

INSTRUMENT CODE

REAGENT CODE

OTHER UNITS, SPECIFY
