

REGISTRATION INSTRUCTIONS & RIQAS POLICIES

CRITERIA FOR PARTICIPATION

This programme is available to any laboratory running Serology for Chagas (*Trypanosoma cruzi*). Qualitative and 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 at 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 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 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. Please quote this number on all correspondence with RIQAS.

B. 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.

C. 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.

D. 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.

E. 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.

F. 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.

G. 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.

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.

H. 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 3 working days. 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.

I. 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 3 working days.

ORDERING RIQAS PRODUCTS

Please ensure your purchase order for this pilot study is placed with your local Randox representative. Participants from UK or Ireland may order products directly from RIQAS with an official order number. Current prices of RIQAS products are available from your local Randox Laboratories representative.

SHIPPING AND RECEIPT OF RIQAS PRODUCTS

Your RIQASKit(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 RIQASNet 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 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

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 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

Due to the research nature of pilot studies, the despatch of reports will take longer than normal.

Reports for each sample will be issued along with a Pilot Study outcome report.

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 the RIQAS Brochure at www.randox.com/external-quality-assessment

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.

PARTICIPANT FEEDBACK, COMPLAINTS & APPEALS

Feedback from participants during the running of the pilot study will be welcomed.
Please send any feedback to mail@riqas.com.

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

E-Mail mail@riqas.com

RIQAS Scheme Co-ordinator: Sarah Fleck

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THIS PROGRAMME HAS NOT BEEN
ACCREDITED TO ISO/IEC 17043:2010

RQ9208 - SEROLOGY CHAGAS PROGRAMME

METHOD QUESTIONNAIRE

Trypanosoma cruzi

CODE	METHOD
TCRALI	<input type="checkbox"/> Abbott Alinity
TCRARC	<input type="checkbox"/> Abbott Architect
TCRABCA	<input type="checkbox"/> Abbott Bioline Chagas Ab
TCRAP	<input type="checkbox"/> Abbott PRISM Chagas
TCRATC	<input type="checkbox"/> ATGen CEL QUEST CHAGAS ELISA
TCRBIC	<input type="checkbox"/> Biocientifica Inmunofluor Chagas
TCRCONC	<input type="checkbox"/> CTK Onsite Chagas Ab combo Rapid test
TCRLIX	<input type="checkbox"/> Diasorin Liaison XL
TCRETE	<input type="checkbox"/> Euroimmun Trypanosoma IgG ELISA
TCRINC	<input type="checkbox"/> InBios Chagas Detect Plus
TCRLDCW	<input type="checkbox"/> LDBIO Chagas Western blot IgG
TCRLBO	<input type="checkbox"/> Lemos Biozyme
TCRLCH	<input type="checkbox"/> Lemos Chagacor
TCRLHA	<input type="checkbox"/> Lemos Chaganosticon
TCRLCHE	<input type="checkbox"/> Lemos Chagatek ELISA
TCRLHC	<input type="checkbox"/> Lemos HAI Polychaco
TCRLRF	<input type="checkbox"/> Lemos Rapid Response
TCRLR	<input type="checkbox"/> Lemos Recombinante Biozyme
TCRRCE	<input type="checkbox"/> Roche Cobas 4000/e411
TCRE8	<input type="checkbox"/> Roche Cobas e402/e801
TCRC6	<input type="checkbox"/> Roche Cobas e601/e602
TCREC8	<input type="checkbox"/> Roche Elecsys Chagas 10146
TCRSDC	<input type="checkbox"/> SD Chagas Ab Rapid
TCRSA9	<input type="checkbox"/> SeraCare ACCURUN 190
TCRSNM	<input type="checkbox"/> SNIBE Maglumi analysers
TCRVIFA	<input type="checkbox"/> Vircell CHAGAS IFA IgG+IgM
TCRVCTM	<input type="checkbox"/> Virclia Chagas TESA IgG + IgM Monotest
TCRWIC	<input type="checkbox"/> Wama Immuno-con CHAGAS
TCRWEL	<input type="checkbox"/> Wiener Lab ELISA lisado
TCRWR3	<input type="checkbox"/> Wiener Lab ELISA recombinante v3.0
TCRWR4	<input type="checkbox"/> Wiener Lab ELISA recombinante v4.0
TCRWHA	<input type="checkbox"/> Wiener Lab IHA
TCRWWLC	<input type="checkbox"/> Wiener WL Check Chagas

Other methods, please specify on enrolment document

INSTRUMENT CODE

REAGENT CODE

UNITS, SPECIFY

OTHER UNITS, SPECIFY