REGISTRATION INSTRUCTIONS & RIQAS POLICIES

CRITERIA FOR PARTICIPATION

This programme is available to any laboratory running the Serology (EBV) parameters listed in this document. Quantitative results will be accepted on this programme. **RATIO results will not be accepted.**

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.

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.

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 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 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 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

PDF reports will be emailed within 72 hours of the FINAL DATE and for those registered for RIQASNet the PDF reports will be available on RIQASNet shortly after.

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.

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.

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
E-Mail mail@riqas.com
RIQAS Scheme Co-ordinator: Sarah Fleck

RANDOX LABORATORIES LTD., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom

RQ9153 - SEROLOGY (EBV) PROGRAMME

METHOD QUESTIONNAIRE

Anti-EBNA IgG U/ml				
CODE		METHOD		
EBNAAI	П	Abbott Alinity		
EBNARC	П	Abbott Architect		
EBNABX	П	Abbott Axsym		
EBNSAN	H	Beckman Access/LXi725		
EBNDXI	Н	Beckman Dxl 600 / 800		
EBNBKE	H	Biokit ELISA		
EBNBIV	Н	Biomerieux VIDAS		
EBNBVK	H	Biomerieux Vironostika ELISA		
EBNBRE	Н	Bio-Rad ELISA		
EBNBRR	Н	Bio-Rad RDT EBV Assay		
EBNDPE	Н	Diagnostic BioProbes ELISA		
EBNDDB	Н	Diamedix/Delta Biologicals ELISA		
EBNDEE	Н	Diasorin ETI-EBNA ELISA		
EBNLIA	Н	Diasorin Liaison		
	Н			
EBNLIX	Н	Diasorin Liaison XL		
EBNDCE	Н	Diesse Chorus ELISA		
EBNDEZ	Н	Diesse Enzywell		
EBNDRG	Н	DRG ELISA		
EBNEUE	Н	Euroimmun ELISA		
EBNEUF	Н	Euroimmun IFA		
EBNHUE	Н	Human ELISA		
EBNIBE	Ы	IBL International ELISA		
EBNMIF	Ы	Meridian Merifluor IFA		
EBNNOV	Ы	Novatec ELISA		
EBNOIC	Ш	Orgenics Immunocomb		
EBNORA	Ы	Orgentec Alegria		
EBNVEC	Ы	Ortho Vitros 3600/5600/ECi		
EBNRAD	Ш	Radim ELISA		
EBNRVT	Ш	Ramintek Virotest		
EBNRBR	Ш	R-Biopharm Ridascreen ELISA		
EBNRCE	Ш	Roche Cobas 4000/e411		
EBNC6	Ш	Roche Cobas 6000 / 8000		
EBNEYS	Ш	Roche Elecsys		
EBNRME	Ш	Roche Modular E170		
EBNDSE	Ш	RPC Diagnostic Systems ELISA		
EBNSQE	Ш	SeraQuest ELISA		
EBNCEN	Ш	Siemens Centaur		
EBNDDV		Siemens/Dade Dimension Vista		
EBNDPC		Siemens/DPC Coat-a-Count		
EBNDPI		Siemens/DPC Immulite 1000		
EBNDP2	Ш	Siemens/DPC Immulite 2000/2500		
EBNSNO	Ш	Siemens Novagnost		
EBNSNM	Ш	SNIBE Maglumi Analysers		
EBNSNM2	Ш	SNIBE Maglumi Analysers II		
EBNTGE	Ш	Technogenetics BEIA		
EBNTEE	Ш	TestLine ELISA		
EBNTOS	Ш	TOSOH		
EBNTRB	Ш	Trinity Biotech ELISA		
EBNVBE	Ш	Vector-Best ELISA		
EBNVE	Ш	Vircell ELISA		
EBNVSE	Ш	Virion/Serion ELISA		
EBNVTE	Ш	Virotech ELISA		
EBNWAE	Ш	Wantai ELISA		
Other methods, please specify on enrolment document				
INSTRUMENT CODE				
REAGENT CODE				
OTHER UNITS, SPECIFY				
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RQ9153 - SEROLOGY (EBV) PROGRAMME

METHOD QUESTIONNAIRE Anti-EBV VCA IgG U/ml CODE METHOD EBVAAI Abbott Alinity **EBVARC** Abbott Architect **EBVABX** Abbott Axsym **EBVAEO** All Diag EBVcheck OPTIMA EBVSAN Beckman Access/LXi725 EBVDXI Beckman DxI 600 / 800 **EBVBCM** Behringwerke Cellognost FRVRKE Biokit ELISA Biomerieux VIDAS **FBVBIV** Biomerieux Vironostika ELISA **FBVBVK EBVBRE** Bio-Rad ELISA **FBVBRR** Bio-Rad RDT EBV EBVDAI Diagnostic Automation Inc EBV **EBVDPE** Diagnostic BioProbes ELISA EBVDDB Diamedix/Delta Biologicals ELISA **EBVDEE** Diasorin ETI-EBV VCA ELISA **EBVLIA** Diasorin Liaison **EBVLIX** Diasorin Liaison XL **EBVDCE** Diesse Chorus ELISA **EBVDEZ** Diesse Enzywell **EBVDRG** DRG ELISA **EBVEUE** Euroimmun ELISA **EBVEUF** Euroimmun IFA EBVFDI Focus EBV-VCA IFA **EBVHUE** Human ELISA **EBVIBE** IBL International ELISA **EBVMIF** Meridian Merifluor IFA EBVMEM Meridian Monospot Latex **EBVNOV** Novatec ELISA **EBVOIC** Orgenics Immunocomb **EBVORA** Orgentec Alegria Ortho Vitros 3600/5600/ECi **EBVVEC** EBVPAM PBM Accusay Mono Radim ELISA EBVRDE FRVRVT Ramintek Virotest **EBVRBR** R-Biopharm Ridascreen ELISA Roche Cobas 4000/e411 **EBVRCE** EBVC6 Roche Cobas 6000 / 8000 **EBVEYS** Roche Elecsys **FBVRMF** Roche Modular E170 **EBVDSE** RPC Diagnostic Systems ELISA **EBVSQE** SeraQuest ELISA **EBVCEN** Siemens Centaur **EBVDDV** Siemens/Dade Dimension Vista **EBVDPC** Siemens/DPC Coat-a-Count EBVDPI Siemens/DPC Immulite 1000 EBVDP2 Siemens/DPC Immulite 2000/2500 **EBVSEN** Siemens Enzygnost **EBVSNO** Siemens Novagnost **EBVSNM** SNIBE Maglumi Analysers EBVSNM2 SNIBE Maglumi Analysers II **EBVTGE** Technogenetics BEIA Test-Line ELISA **EBVTEE EBVTOS** TOSOH Trinity Biotech ELISA **EBVTRB EBVVBE** Vector-Best ELISA **EBVVE** Vircell ELISA **EBVVC** Vircell VIRCLIA **EBVVSE** Virion/Serion ELISA Virotech ELISA **EBVVTE EBVWAE** Wantai ELISA

Other methods, please specify on enrolment document

NSTRUMENT CODE	
REAGENT CODE	
OTHER UNITS, SPECIFY	

RQ9153 - SEROLOGY (EBV) PROGRAMME

METHOD QUESTIONNAIRE

Anti-EBV VCA IgM U/ml CODE METHOD EBVAAI Abbott Alinity **EBVARC** Abbott Architect **EBVCIM** Alere Clearview IM / IM II **EBVAEO** All Diag EBVcheck OPTIMA **EBVBKE** Biokit ELISA Biomerieux Vidas Biomerieux Vironostika ELISA FRVRIV EBVBVK EBVBRE Bio-Rad ELISA **EBVBRR** Bio-Rad RDT EBV **EBVDAI** Diagnostic Automation Inc EBV **EBVDPE** Diagnostic BioProbes ELISA Dialab Diaquick Mononucleosis Cassette Diamedix/Delta Biologicals ELISA FBVDDQ EBVDDB EBVDEE Diasorin ETI-EBV VCA ELISA **EBVLIA** Diasorin Liaison **EBVLIX** Diasorin Liaison XL **EBVDCE** Diesse Chorus ELISA EBVDEZ Diesse Enzywell DRG ELISA Euroimmun ELISA **FBVDRG** EBVEUE **EBVHUE** Human ELISA IBL International ELISA EBVIBE EBVNOV Novatec ELISA EBVORA Orgentec Alegria EBVRDE Radim ELISA **EBVRVT** Ramintek Virotest EBVRBR R-Biopharm Ridascreen ELISA RPC Diagnostic Systems ELISA SeraQuest ELISA **EBVDSE FBVSOF** EBVCEN Siemens Centaur **EBVSEN** Siemens Enzygnost EBVDP2 Siemens Immulite 2000 **EBVSNO** Siemens Novagnost **EBVSNM** SNIBE Maglumi Analysers EBVTGE Technogenetics BEIA Test-Line ELISA EBVTEE EBVTRB Trinity Biotech ELISA **EBVVBE** Vector-Best ELISA EBVVE EBVVC Vircell ELISA Vircell VIRCLIA EBVVSE Virion/Serion ELISA Virotech ELISA **EBVVTE** Other methods, please specify on enrolment document INSTRUMENT CODE REAGENT CODE OTHER UNITS, SPECIFY