REGISTRATION INSTRUCTIONS & RIQAS POLICIES

CRITERIA FOR PARTICIPATION

This programme is available to any laboratory routinely involved in the identification and suseptibility testing of the microbes listed in this document.

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.

Following this introduction section is the method questionnaire which indicates the method for identification, Guidelines and antibiotics available. On the method questionnaire, state your method for identification and Guideline that you use in your laboratory. If codes are not available for your method or guideline, please state the details clearly in the section at the end of the enrolment document. If you use any antibiotics that are not listed in the method questionnaire please also state these clearly at the end of the enrolment document. Please do not use Brand names.

The quidelines referred to above are in relation to antimicrobial susceptibility testing. If unsure please contact RIQAS.

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 guote 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 / 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 the 'Registration of Assay Details' section of the enrolment document.

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 no method/guideline is available in the method questionnaire for your test, please state the details clearly in the section at the end of the enrolment document

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

H. UPDATING ASSAY DETAILS

It is possible to change your method and Guideline during a cycle. Please email mail@riqas.com. Please include your laboratory reference number and the details of the update required.

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 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.

Case studies are provided for each sample. These can also be downloaded from RigasNet

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

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RQ9197 - MICROBIOLOGY - Bacterial Identification

METHOD QUESTIONNAIRE

Bacterial Identification METHOD Alifax HB&L VITEK 2 (all models) Alifax Sidecar VITEK MS Autoscan 4 Real Time PCR QuantStudio 5 **BACTEC** BD Phoenix (all models) **BIOMIC V3** Biomerieux API Biomerieux BACT/ALERT Erbascan Biomerieux Biofire BioRad Adagio **Conventional Tests** D2 Mini **DNA Sequencing ERBA ENTEROTest 24** MALDI-ToF Microflex LT/SH MicroScan WalkAway Mindray AF Systems Sensititre Aris 2X

Guidelines (antimicrobial susceptibility testing standards)

| BSAC |
|--------|
| CA-SFM |
| CLSI |
| EUCAST |
| NWGA |

Other Guidelines, please specify on enrolment document

Other methods, please specify on enrolment document

Antibiotics

Ceftaroline

Ceftazidime

Ceftobiprole

Ceftriaxone

Ceftazidime/Avibactam

Ceftolozane/Tazobactam

Cephalothin Amikacin Amoxicillin Chloramphenicol Amoxicillin/Clavulanic Acid Ciprofloxacin Amphotericin B Clarithromycin Clindamycin Ampicillin Ampicillin/Sulbactam Clotrimazole Anidulafungin Cloxacillin Augmentin Colistin Azithromycin Cotrimoxazole Aztreonam Daptomycin Benzylpenicillin Doripenem Caspofungin Doxycycline Econazole Cefaclor Enrofloxacin Cefazolin Ertapenem Cefepime Cefiderocol FDC30 Erythromycin Cefixime Flucloxacillin Cefodime Fluconazole Cefoperazone Flucytosin Cefoperazone/Sulbactam Fosfomycin Cefotaxime Fusidic Acid Cefoxitin Gentamicin Cefpodoxime

Minocycline Moxifloxacin Mupirocin Nalidixic Acid Netilmicin Nitrofurantoin Norfloxacin Nystatin Ofloxacin Oxacillin Penicillin Piperacillin Piperacillin/Tazobactam Polimixin B Quinupristin/Dalopristin Rifampicin Gentamicin high level Spectinomicin Imipenem Streptomycin Imipenem/Cilastatin/Relebactam Streptomycin high level Itraconazole **Tazobactam**

Meropenem

Methoxazole

Metronidazole

Methicillin

Micafungin

Miconazole

Teicoplanin

Temocillin

Telithromycin

Tigecycline Tobramycin

Trimethoprim/Sulfamethoxazole

Vancomycin Voriconazole

 Cefuroxime
 Linezolid
 Tetracycline

 Cephalexin
 Mecillinam
 Ticarcillin/Clavulanic Acid

Kanamycin

Ketoconazole

Levofloxacin

If additional antibiotics would be routinely used, please specify on enrolment document

RQ9197-MICROBIOLOGY

IDENTIFICATION LIST

Microorganism

Alicyclobacillus

Alicyclobacillus acidocaldarius

Bacteroides

Bacteroides bivius Bacteroides distasonis Bacteroides fragilis

Bacteroides fragilis group Bacteroides ovatus

Bacteroides splanchnicus

Bacteroides thetaiotaomicron

Bacteroides ureolyticus Bacteroides vulgatus

Campylobacter

Campylobacter coli Campylobacter fetus Campylobacter jejuni

Candida

Candida albicans Candida auris

Candida dubliniensis Candida glabrata Candida nivariensis

Candida parapsilosis

Citrobacter

Citrobacter amalonaticus Citrobacter braakii Citrobacter freundii Citrobacter koseri

Clostridioides

Clostridioides difficile

Clostridium

Clostridium bifermentans Clostridium clostridioforme Clostridium histolyticum Clostridium innocuum

Clostridium novyi Clostridium perfringens

Clostridium ramosum Clostridium septicum Clostridium sordellii

Clostridium sporogenes Clostridium tertium

Clostridium tetani **Enterobacter**

Enterobacter agglomerans Enterobacter asburiae Enterobacter cloacae Enterobacter gergoviae

Enterobacter hormaechei Enterobacter kobei

Microorganism

Enterobacter ludwigii Enterobacter nimipressuralis

Enterobacter sakazakii

Enterococcus

Enterococcus casseliflavus Enterococcus faecalis Enterococcus faecium Enterococcus gallinarum Enterococcus hirae

Enterococcus raffinosus

Escherichia Escherichia coli

Escherichia coli (0103:H11) Escherichia coli (0111:H8) Escherichia coli (0121:H19) Escherichia coli (0145:NM) Escherichia coli (0157:H7) Escherichia coli (026:H11) Escherichia coli (045:H2)

Haemophilus

Haemophilus influenzae Haemophilus parainfluenzae

Klebsiella

Klebsiella aerogenes Klebsiella oxytoca Klebsiella ozaenae Klebsiella pneumoniae

Listeria

Listeria innocua

Listeria monocytogenes

Moraxella

Moraxella catarrhalis

Neisseria

Neisseria gonorrhoeae Neisseria lactamica Neisseria meningitidis Neisseria subflava

Proteus

Proteus mirabilis Proteus penneri Proteus vulgaris **Pseudomonas**

Pseudomonas aeruginosa Pseudomonas fluorescens Pseudomonas putida Pseudomonas stutzeri

Saccharomyces

Saccharomyces cerevisiae

Salmonella

Salmonella enterica

Microorganism

Serratia

Serratia liquefaciens Serratia marcescens Serratia Plymuthica Serratia rubidaea

Shigella

Shigella boydii Shigella dysenteriae Shigella flexneri Shigella sonnei Staphylococcus

Staphylococcus aureus Staphylococcus delphini Staphylococcus epidermidis Staphylococcus haemolyticus Staphylococcus hominis Staphylococcus hyicus Staphylococcus intermedius Staphylococcus lugdunensis

Staphylococcus pseudintermedius Staphylococcus saccharolyticus Staphylococcus saprophyticus Staphylococcus schleiferi

Streptococcus

Streptococcus agalactiae Streptococcus alactolyticus Streptococcus anginosus Streptococcus bovis Streptococcus dysgalactiae Streptococcus equinus Streptococcus gallolyticus Streptococcus infantarius Streptococcus intermedius

Streptococcus mitis

Streptococcus pneumoniae Streptococcus pyogenes

Vibrio

Vibrio alginolyticus Vibrio cholerae Vibrio cincinnatiensis Vibrio fluvialis Vibrio furnissii Vibrio harveyi Vibrio metschnikovii Vibrio mimicus

Vibrio parahaemolyticus

Vibrio vulnificus

Zygosaccharomyces

Zygosaccharomyces rouxii