

RIQAS

RANDOX INTERNATIONAL QUALITY ASSESSMENT SCHEME

**METHOD QUESTIONNAIRE
CARDIAC PROGRAMME**

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 Cardiac assays listed in this document. Quantitative results will be accepted on this programme.

INTRODUCTION

Method questionnaires are available for all routine *RIQAS* Programmes. 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. 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

1. 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.

NB. For enzymes, it is important for you to record the temperature at which the assay is performed.

Once your method questionnaire has been completed, you must transfer the information onto your enrolment document.

2. ENROLMENT DOCUMENT:- To be returned to *RIQAS*

Please be aware that it may take up to 3 weeks to process enrolment documents.

A. LABORATORY REFERENCE NUMBER

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.

B. 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.

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. CONTACT DETAILS

It is important to state the name and full address details of the Quality Assessment Officer or contact person who will receive all correspondence and routine reports during the cycle. Please also state the company name of the Randox representative who is supplying you with the *RIQAS* product under 'Randox Representative'.

E. *RIQAS* Net

RIQAS Net is a web-based online method for result entry/method changes/viewing of released reports. Reports will be sent to up to 3 email addresses as PDF files. Internet access and login details are required for *RIQAS* Net and Adobe Reader is required for viewing reports. If you wish to use *RIQAS* Net 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.

F. 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.

G. GROUP REPORTS

It is possible to enrol **multiple instruments** within your laboratory. **Kindly complete separate enrolment documents for each instrument.** 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.

H. REGISTRATION OF METHODS

Complete the 'Registration of Methods' section for all required parameters using the codes you selected on your method questionnaire. 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.

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.

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.

I. CHANGES DURING A CYCLE

Please inform *RIQAS* of any change to contact details as soon as possible. It is also possible to change your unit, method, instrument or reagent classification during a cycle.

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.

Participants who use *RIQAS* Net: Changes can be made in the Method Changes 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 and the assay details will appear. 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 receipt of method changes *RIQAS* staff will manually process and update your assay details which will then be uploaded onto *RIQAS* Net. It is possible to submit results and method changes at the same time as method changes will be made before results are submitted.

LABORATORY REFERENCE NUMBERS, RETURN SHEETS & LOOK-UP TABLES

On receipt of your enrolment document *RIQAS* will generate a **Laboratory Reference Number** for your laboratory and additional numbers for associated laboratories or multiple instruments if requested. If you are registering for the first time you will be sent *RIQAS* literature, which will enable you to understand the *RIQAS* process and interpret your reports.

Participants using *RIQAS* Net will receive an email containing their login information. Once you have successfully logged in to *RIQAS* Net you will see your various laboratory reference numbers for each registered programme.

Participants who do not use *RIQAS* Net 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*.

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 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 receipt of your *RIQAS* kit, please check that:

- a) it is the product you ordered
- b) the tamper-proof label has not been broken
- c) the kit contains detailed Instructions For Use (IFU), including material characteristics, preparation, stability, storage and safety
- d) the correct number of samples are present as indicated on the IFU
- e) 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. 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. While *RIQAS* permits the submission of late or corrected results under the circumstances described below, routine reports are clearly marked to indicate late and corrected results.

LATE RESULTS

Results received after the FINAL DATE will be processed retrospectively. Participants will still receive their report which will record late results as "NO RESULTS" until reprocessing is complete. Please ensure that any late results you wish to submit reach us by no later than the final date of the following sample. Any results received after this date will not be entered.

CORRECTED RESULTS

Participants will be permitted to submit corrected results up to 4 weeks after the final date of the sample. While a new report will not be issued, corrected results will be processed retrospectively and results can be viewed on subsequent reports.

DESPATCH OF REPORTS

Results will normally be processed within 2 days of the FINAL DATE. PDF reports will be sent as soon as the results have been processed and for those registered for *RIQAS* Net the PDF reports will be available on *RIQAS* Net shortly after. Printed reports usually take a further 1-3 days to print and despatch.

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 their laboratory accreditation bodies 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.

CERTIFICATES OF PARTICIPATION

Complimentary certificates of participation for each *RIQAS* programme are available to participants at the **end of the current cycle**, provided that **at least 50%** of results have been returned. The certificate will specify the cycle, programme and the LABORATORY / HOSPITAL NAME specified in the address details of the enrolment document. Modified certificates may be requested through your local Randox representative. At the end of a cycle, a list of all eligible labs will be sent to the local Randox representative who will confirm the Laboratory/Hospital Name. This list will be returned to the *RIQAS* department and certificates printed according to the details sent by the local Randox representative. If any modifications or additions are required after this list has been finalised an administration fee will be charged.

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 & RIGHT TO APPEAL

In order to ensure that *RIQAS* provides an appropriate and satisfying service, all participants will be provided with a feed-back questionnaire towards the end of a cycle. We would invite you to 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 appeal against the interpretation of their results or assessment of their performance through correspondence with the local Randox Laboratories representative or by contacting *RIQAS* directly.

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.

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

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

Revised November 2011

THIS PROGRAMME IS ACCREDITED BY UKAS TO ILAC

G13:08/2007



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CARDIAC PROGRAMME

METHOD QUESTIONNAIRE

CK, Total U/l

- | CODE | METHOD |
|-------|---|
| CKTD | <input type="checkbox"/> Dithioerythritol (DTE) |
| CKDIF | <input type="checkbox"/> Dithioerythritol (DTE) IFCC correlated |
| CKTM | <input type="checkbox"/> Monothioglycerol |
| CKTIF | <input type="checkbox"/> CK-NAC (IFCC) |
| CKTSE | <input type="checkbox"/> CK-NAC serum start |
| CKTSU | <input type="checkbox"/> CK-NAC substrate start |
| CKTDC | <input type="checkbox"/> Ortho Vitros MicroSlide Systems |
| CKTDT | <input type="checkbox"/> Vitros DT60/DT60 II/DTSC II |
| | <input type="checkbox"/> Vitros Slide Generation Number <input type="text"/> <input type="text"/> |
| CKO | <input type="checkbox"/> Other methods, please specify on enrolment document |

INSTRUMENT CODE

REAGENT CODE

RESULTS REPORTED AT 25°C 30°C 37°C

OTHER UNITS, SPECIFY

CK-MB, Activity U/l

- | CODE | METHOD |
|-------|---|
| CKMIF | <input type="checkbox"/> Immunoinhibition (IFCC) |
| CKMSE | <input type="checkbox"/> Immunoinhibition, serum start |
| CKMSU | <input type="checkbox"/> Immunoinhibition, substrate start |
| CKMDC | <input type="checkbox"/> Ortho Vitros MicroSlide Systems |
| CKMDT | <input type="checkbox"/> Vitros DT60/DT60 II/DTSC II |
| | <input type="checkbox"/> Vitros Slide Generation Number <input type="text"/> <input type="text"/> |
| CKMIO | <input type="checkbox"/> Other methods, please specify on enrolment document |

INSTRUMENT CODE

REAGENT CODE

RESULTS REPORTED AT 25°C 30°C 37°C

OTHER UNITS, SPECIFY

CK-MB, Mass ng/ml

- | CODE | METHOD |
|-------|--|
| CKARC | <input type="checkbox"/> Abbott Architect |
| CKABX | <input type="checkbox"/> Abbott Axsym |
| CKAIS | <input type="checkbox"/> Abbott i-STAT |
| CKABB | <input type="checkbox"/> Abbott IMx |
| CKSAN | <input type="checkbox"/> Beckman Access |
| CKDXI | <input type="checkbox"/> Beckman Dxl 600 / 800 |
| CKVID | <input type="checkbox"/> bioMerieux, VIDAS |
| CKLIA | <input type="checkbox"/> Byk, Liaison |
| CKVEC | <input type="checkbox"/> Ortho Vitros, 3600 / 5600 / ECi |
| CKEV | <input type="checkbox"/> Randox Evidence / Investigator |
| CKRAM | <input type="checkbox"/> Response Biomedical Ramp |
| CKRCR | <input type="checkbox"/> Roche Cardiac Reader |
| CKRH | <input type="checkbox"/> Roche Cobas h232 |
| CKEYS | <input type="checkbox"/> Roche Elecsys / E170 / c6000 / e411 |
| CKCC | <input type="checkbox"/> Siemens/Bayer ACS180 |
| CKCEN | <input type="checkbox"/> Siemens/Bayer ADVIA Centaur |
| CKBAY | <input type="checkbox"/> Siemens/Bayer Immuno 1 |
| CKDD | <input type="checkbox"/> Siemens/Dade Dimension / RxL / Max |
| CKDO | <input type="checkbox"/> Siemens/Dade Opus |
| CKSIS | <input type="checkbox"/> Siemens/Dade Stratus |
| CKDPI | <input type="checkbox"/> Siemens/DPC Immulite 1000 |
| CKDP2 | <input type="checkbox"/> Siemens/DPC Immulite 2000 |
| CKDP5 | <input type="checkbox"/> Siemens/DPC Immulite 2500 |
| CKTOS | <input type="checkbox"/> Tosoh |
| CKMMO | <input type="checkbox"/> Other methods, please specify on enrolment document |

INSTRUMENT CODE

REAGENT CODE

OTHER UNITS, SPECIFY

CARDIAC PROGRAMME

METHOD QUESTIONNAIRE

HOMOCYSTEINE $\mu\text{mol/l}$

CODE	METHOD
HOARC	<input type="checkbox"/> Abbott Architect
HOABX	<input type="checkbox"/> Abbott Axsym
HOABB	<input type="checkbox"/> Abbott IMx
HOAU4	<input type="checkbox"/> Beckman AU400 / 600 / 640 / 2700 / 5400
HOBEK	<input type="checkbox"/> Beckman Synchron LX20
HOHP	<input type="checkbox"/> HPLC
HOEIA	<input type="checkbox"/> Manual - E.I.A.
HORAM	<input type="checkbox"/> Response Biomedical Ramp
HOINT	<input type="checkbox"/> Roche Integra
HOCEN	<input type="checkbox"/> Siemens/Bayer ADVIA Centaur
HONEP	<input type="checkbox"/> Siemens/Dade Behring Nephelometer
HODP2	<input type="checkbox"/> Siemens/DPC Immulite 2000 / 2500
HOO	<input type="checkbox"/> Other methods, please specify on enrolment document

INSTRUMENT CODE

REAGENT CODE

OTHER UNITS, SPECIFY

MYOGLOBIN ng/ml

CODE	METHOD
MYARC	<input type="checkbox"/> Abbott Architect
MYABX	<input type="checkbox"/> Abbott Axsym
MYSAN	<input type="checkbox"/> Beckman Access
MYDXI	<input type="checkbox"/> Beckman Dxl 600 / 800
MYVID	<input type="checkbox"/> bioMerieux, VIDAS
MYLIA	<input type="checkbox"/> Byk, Liaison
MYEV	<input type="checkbox"/> RandoxEvidence / Investigator
MYRDX	<input type="checkbox"/> Randox Daytona / Imola
MYRCR	<input type="checkbox"/> Roche Cardiac Reader
MYRH	<input type="checkbox"/> Roche Cobas h232
MYEYS	<input type="checkbox"/> Roche Elecsys / E170 / c6000 / e411
MYHIT	<input type="checkbox"/> Roche Hitachi
MYINT	<input type="checkbox"/> Roche Integra
MYCEN	<input type="checkbox"/> Siemens/Bayer ADVIA Centaur
MYDD	<input type="checkbox"/> Siemens/Dade Dimension
MYBN	<input type="checkbox"/> Siemens/Dade Nephelometer
MYDO	<input type="checkbox"/> Siemens/Dade Opus
MYST	<input type="checkbox"/> Siemens/Dade Stratus
MYDPI	<input type="checkbox"/> Siemens/DPC Immulite 1000
MYDP2	<input type="checkbox"/> Siemens/DPC Immulite 2000
MYDP5	<input type="checkbox"/> Siemens/DPC Immulite 2500
MYTOS	<input type="checkbox"/> Tosoh
MYO	<input type="checkbox"/> Other methods, please specify on enrolment document

INSTRUMENT CODE

REAGENT CODE

OTHER UNITS, SPECIFY

CARDIAC PROGRAMME

METHOD QUESTIONNAIRE

TROPONIN I ng/ml

CODE	METHOD
TIARC	<input type="checkbox"/> Abbott Architect
TIABX	<input type="checkbox"/> Abbott Axsym
TIABA	<input type="checkbox"/> Abbott Axsym ADV
TIAIS	<input type="checkbox"/> Abbott i-STAT
TISAN	<input type="checkbox"/> Beckman Access
TIDXI	<input type="checkbox"/> Beckman, Dxl 600 / 800 1st gen.
TIVID	<input type="checkbox"/> bioMerieux VIDAS
TIVIU	<input type="checkbox"/> bioMerieux VIDAS Ultra
TILIA	<input type="checkbox"/> Byk, Liaison
TIMP	<input type="checkbox"/> Mitsubishi Pathfast
TIVEC	<input type="checkbox"/> Ortho Vitros, 3600 / 5600 / ECi
TIEV	<input type="checkbox"/> Randox Evidence / Investigator
TIRAM	<input type="checkbox"/> Response Biomedical Ramp
TIEYS	<input type="checkbox"/> Roche Elecsys / E170 / c6000 / e411
TICC	<input type="checkbox"/> Siemens/Bayer ACS 180
TICEN	<input type="checkbox"/> Siemens/Bayer ADVIA Centaur
TIBAY	<input type="checkbox"/> Siemens/Bayer Immuno1
TIDDV	<input type="checkbox"/> Siemens/Dade Dimension EXL / Vista
TIDD	<input type="checkbox"/> Siemens/Dade Dimension RxL / Max / Xpand
TIDO	<input type="checkbox"/> Siemens/Dade Opus
TIST	<input type="checkbox"/> Siemens/Dade Stratus
TIDPI	<input type="checkbox"/> Siemens/DPC Immulite 1000
TIDP2	<input type="checkbox"/> Siemens/DPC Immulite 2000
TIDP5	<input type="checkbox"/> Siemens/DPC Immulite 2500
TITOS	<input type="checkbox"/> Tosoh
TIDC	<input type="checkbox"/> Vitros
TIO	<input type="checkbox"/> Other methods, please specify on enrolment document

INSTRUMENT CODE

REAGENT CODE

OTHER UNITS, SPECIFY

TROPONIN T ng/ml

CODE	METHOD
TTRCR	<input type="checkbox"/> Roche Cardiac Reader When your RIQAS sample gives a result of less than 0.1 ng/ml or less than 0.03 ng/ml ("negative", "<0.1" or "< 0.03"), please simply submit the actual value (0.03 or 0.1)
TTRH	<input type="checkbox"/> Roche Cobas h232
TTEYS	<input type="checkbox"/> Roche Cobas Troponin T kits
TTRHS	<input type="checkbox"/> Roche Cobas Troponin T hs kits

INSTRUMENT CODE

REAGENT CODE

OTHER UNITS, SPECIFY
