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. 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. GROUP REPORTS AND MULTIPLE REGISTRATIONS

Assessment of the same parameters on multiple systems - It is possible to enrol multiple instruments within your laboratory, up to five instruments per programme (volume permitting) can be added at no extra cost for comparative performance assessment. 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. 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. 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.

E. RIQAS**Net**

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.

F. 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.

G. 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, SDPA and z-score. 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.

H. 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.

I. 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.**

J. 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.

K. 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.

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 Cerificate 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. 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. Information regarding the calculations and scores used to evaluate participants' performance on RIQAS Reports can be found following log in to RIQASNet, in a document entitled "Evaluation of Performance".

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.

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 is accredited by UKAS TO ISO/IEC 17043:2010 via Fixed Scope

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

RQ9141 - IMMUNOASSAY SPECIALITY 1

METHOD QUESTIONNAIRE

Anti-TG (kU/l)

CODE		METHOD
ATGARC	☐	Abbott Architect/ Alinity
ATGABX	☐	Abbott Axsym
ATGAEA	☐	Aida EIA
ATGAKE	☐	Aesku Diagnostics ELISA
ATGABC	☐	Autobio CLIA
ATGSAN	☐	Beckman Access/LXi725
ATGDXI	☐	Beckman DxI 600/800
ATGBDX9	☐	Beckman DxI 9000
ATGBHR	☐	Biocode Hycel RIA
ATGBIV	☐	Biomerieux Vidas
ATGBRR	☐	Brahms RIA
ATGBRK	☐	Brahms Kryptor
ATGCDG	☐	CDG Q-Strip
ATGCIR	☐	CIS RIA
ATGCAX	☐	Cormay Auryx ECLIA
ATGDME	☐	DiaMetra ELISA
ATGLIA	☐	DiaSorin Liaison
ATGLIX	☐	DiaSorin Liaison XL
ATGBYK	☐	DiaSorin RIA
ATGDCH	☐	Diesse Chorus
ATGDRC	☐	DIRUI CM Series
ATGEUE	☐	Euroimmun ELISA
ATGFJL	☐	Fujirebio Lumipulse G Series
ATGHUE	☐	Human ELISA
ATGHYE	☐	Hycor ELISA
ATGIEL	☐	Inova Microelisa
ATGIZR	☐	Izotop Anti hTG RIA KIT
ATGSLT	☐	Lifotronic eCL
ATGMAI	☐	Maccura I Series
ATGMME	☐	Medipan Medizym EIA
ATGMC2	☐	Mindray CL 8000i/6000i/2000i/1200i/1000i
ATGMC3	☐	Mindray CL 900i
ATGORA	☐	Orgentec Alegria
ATGDEL	☐	Perkin Elmer DELFIA Xpress/AutoDELFIA
ATGPHU	☐	Phadia/ImmunoCAP 100/250
ATGPHE	☐	Phadia ELISA
ATGEVE	☐	Randox Evolution
ATGRCE	☐	Roche Cobas 4000 / e411
ATGC6	☐	Roche Cobas e601/602
ATGE8	☐	Roche Cobas e402/e801
ATGEYS	☐	Roche Elecsys
ATGRME	☐	Roche Modular E170
ATGSNM	☐	SNIBE Maglumi analysers
ATGSNM2	☐	SNIBE Maglumi analysers II
ATGSRR	☐	SEAC Radim RIA CT
ATGSPA	☐	Serodia Particle Agglutination
ATGSAI	☐	Siemens Atellica IM
ATGSA2	☐	Siemens Atellica IM aTgll
ATGCEN	☐	Siemens Centaur
ATGCE2	☐	Siemens Centaur aTgll
ATGDPI	☐	Siemens/DPC Immulite 1000
ATGDP2	☐	Siemens/DPC Immulite 2000/2500
ATGTOC	☐	TOSOH AIA CL-Series
ATGTOS	☐	TOSOH AIA Series
ATGZER	☐	ZenTech RIA

Other methods, please specify on enrolment document

INSTRUMENT CODE	
REAGENT CODE	
OTHER UNITS, SPECIFY	

Anti-TPO (kU/l)

CODE		METHOD
ATPARC	☐	Abbott Architect/ Alinity
ATPABX	☐	Abbott Axsym
ATPAEA	☐	Aida EIA
ATPAKE	☐	Aesku Diagnostics ELISA
ATPABC	☐	Autobio CLIA
ATPSAN	☐	Beckman Access/LXi725
ATPDXI	☐	Beckman DxI 600/800
ATPBDX9	☐	Beckman DxI 9000
ATPBIV	☐	Biomerieux Vidas
ATPBRR	☐	Brahms RIA
ATPBRK	☐	Brahms Kryptor
ATPCDG	☐	CDG Q-Strip
ATPCIR	☐	CIS RIA
ATPCAX	☐	Cormay Auryx ECLIA
ATPIDS	☐	Diagnostic System Anti TPO ELISA
ATPLIA	☐	DiaSorin Liaison
ATPLIX	☐	DiaSorin Liaison XL
ATPBYK	☐	DiaSorin RIA
ATPDCH	☐	Diesse Chorus
ATPDRC	☐	DIRUI CM Series
ATPEPE	☐	Epitope Diagnostics ELISA
ATPEUE	☐	Euroimmun ELISA
ATPFJL	☐	Fujirebio Lumipulse G Series
ATPHYE	☐	Hycor ELISA
ATPIEL	☐	Inova Microelisa
ATPIZER	☐	Izotop Anti hTPO RIA KIT
ATPSLT	☐	Lifotronic eCL
ATPMAI	☐	Maccura I Series
ATPMME	☐	Medipan Medizym EIA
ATPMC2	☐	Mindray 8000i/6000i/2000i/1200i/1000i
ATPMC3	☐	Mindray CL900i
ATPORA	☐	Orgentec Alegria
ATPDEL	☐	Perkin Elmer DELFIA Xpress/AutoDELFIA
ATPPHU	☐	Phadia/ImmunoCAP 100/250
ATPPHE	☐	Phadia ELISA
ATPEVE	☐	Randox Evolution
ATPRCE	☐	Roche Cobas 4000 / e411
ATPC6	☐	Roche Cobas e601 / 602
ATPC8	☐	Roche Cobas e402/e801
ATPRME	☐	Roche Modular E170
ATPEYS	☐	Roche Elecsys
ATPSRR	☐	SEAC Radim RIA CT
ATPSAI	☐	Siemens Atellica IM
ATPSAI2	☐	Siemens Atellica IM (aTPOII)
ATPCEN	☐	Siemens Centaur
ATPCEN2	☐	Siemens Centaur (aTPOII)
ATPDPI	☐	Siemens/DPC Immulite 1000
ATPDP2	☐	Siemens/DPC Immulite 2000/2500
ATPTOC	☐	Tosoh AIA-CL Series
ATPTOS	☐	Tosoh AIA Series
ATPZER	☐	ZenTech RIA

Other methods, please specify on enrolment document

INSTRUMENT CODE	
REAGENT CODE	
OTHER UNITS, SPECIFY	

RQ9141 - IMMUNOASSAY SPECIALITY 1

METHOD QUESTIONNAIRE

C-Peptide nmol/L

CODE		METHOD
CPTARC	☐	Abbott Architect/ Alinity
CPTADR	☐	Adaltis RIA
CPABC	☐	Autobio CLIA
CPSAN	☐	Beckman Access C-Peptide
CPCDG	☐	CDG Q-Strip
CPTCIR	☐	CIS RIA
CPCII	☐	CIS BIO IRMA
CPTLIA	☐	DiaSorin Liaison
CPTLIX	☐	DiaSorin Liaison XL
CPTDIR	☐	DIAsource RIA
CPDRC	☐	DIRUI CM Series
CPTDRG	☐	DRG ELISA
CPTDSL	☐	DSL RIA
CPTFJL	☐	Fujirebio Lumipulse G Series
CPTILM	☐	ILMA
CPTIRM	☐	Immunotech IRMA
CPTMC2	☐	Mindray CL 8000i/6000i/2000i/1200i/1000i
CPTMC3	☐	Mindray CL900i
CPTMOE	☐	Monobind Inc. ELISA
CPTVEC	☐	Ortho Vitros 3600/5600/ECi/XT 7600

CODE		METHOD
CPTRAA	☐	Radim Alisei
CPTRAD	☐	RADIM RIA
CPTEV	☐	Randox Evidence / Investigator
CPTRCE	☐	Roche Cobas 4000 / e411
CPTC6	☐	Roche Cobas e601/602
CPTE8	☐	Roche Cobas e402/e801
CPTRME	☐	Roche Modular E170
CPTEYS	☐	Roche Elecsys
CPSAI	☐	Siemens Atellica IM
CPSA12	☐	Siemens Atel IM (Rgt lot 207 &cal lot 09&up)
CPTCEN	☐	Siemens Centaur
CPCEN2	☐	Siemens Cen (Rgt lot 206 & cal lot 08&up)
CPTDPI	☐	Siemens/DPC Immulite 1000
CPTDP2	☐	Siemens/DPC Immulite 2000/2500
CPTTOS	☐	Tosoh AIA Series
CPTTOC	☐	Tosoh AIA-CL Series
CPVBE	☐	Vector Best ELISA
CPC2	☐	Wantai Caris 200
CPW2	☐	Wantai Wan200+

Other methods, please specify on enrolment document

INSTRUMENT CODE	
REAGENT CODE	
OTHER UNITS, SPECIFY	

IGF-1 ug/l

CODE		METHOD
IGFABC	☐	Autobio CLIA
IGFBCR	☐	Bioclone RIA
IGFCIS	☐	CIS IRMA
IGFCIR	☐	CIS RIA
IGFDME	☐	DiaMetra ELISA
IGFLIA	☐	DiaSorin Liaison
IGFLIX	☐	DiaSorin Liaison XL
IFGDIE	☐	DIAsource ELISA
IGFDIR	☐	DIAsource RIA
IGFDRG	☐	DRG ELISA
IGFDSE	☐	DSL ELISA
IGFDSI	☐	DSL IRMA
IGFDSL	☐	DSL RIA
IGFIBL	☐	IBL ELISA

CODE		METHOD
IGFIDE	☐	IDS ELISA
IGFIDC	☐	IDS CLIA
IGFIDI	☐	IDS IRMA
IGFIMI	☐	Immunotech IRMA
IGFIBE	☐	Invitrogen Biosource ELISA
IGFMDE	☐	Mediagnost IGF-1 ELISA
IGFPHA	☐	Phoenix Airmid ELISA
IGFRCE	☐	Roche Cobas 4000 / e411
IGFC6	☐	Roche Cobas 6000 / 8000
IGFRME	☐	Roche Modular E170
IGFEYS	☐	Roche Elecsys
IGFDPI	☐	Siemens/DPC Immulite 1000
IGFDPII	☐	Siemens/DPC Immulite 1000 Re-std
IGFDP2	☐	Siemens/DPC Immulite 2000/2500
IGFDP2I	☐	Siemens/DPC Immulite 2000/2500 Re-std
IGFSNB	☐	SNIBE Maglumi Analysers

Other methods, please specify on enrolment document

INSTRUMENT CODE	
REAGENT CODE	
OTHER UNITS, SPECIFY	

Insulin uU/ml

CODE		METHOD
INAAI	☐	Abbott Alinity I
INARC	☐	Abbott Architect
INABX	☐	Abbott AxSym
INABB	☐	Abbott Imx
INAPE	☐	Alfa Prime ELISA
INABC	☐	Autobio CLIA
INSAN	☐	Beckman Access/LXi725
INDXI	☐	Beckman Dxl 600/800
INBIG	☐	Biosource Gamma counter
INCBE	☐	Calbiotech ELISA
INCDG	☐	CDG Q-Strip
INCIS	☐	CIS IRMA
INCIR	☐	CIS RIA coated blue
INCLI	☐	Clinipro ELISA
INDAE	☐	Diagnostic Automation ELISA
INLIA	☐	Diasorin Liaison
INLIX	☐	Diasorin Liaison XL
INDIA	☐	Diasource IRMA
INDRC	☐	DIRUI CM Series
INELI	☐	ELISA
INFJL	☐	Fujirebio Lumipulse G Series
INIMI	☐	Immunotech IRMA
INIVL	☐	Invitron Luminescence
INIZG	☐	Izotop Gamma Counter
INSLT	☐	Lifotronic eCL
INLIR	☐	Linco RIA
INMC2	☐	Mindray CL 8000i/6000i/2000i/1200i/1000i
INMC3	☐	Mindray CL 900i

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RQ9141 - IMMUNOASSAY SPECIALITY 1

METHOD QUESTIONNAIRE

Insulin uU/ml

CODE		METHOD
INMOE	☐	Monobind Inc. ELISA
INNOV	☐	Novatec ELISA
INVEC	☐	Ortho Vitros 3600/5600/ECi/XT 7600
INDEL	☐	Perkin Elmer DELFIA
INWW	☐	Perkin Elmer Wizard
INRAA	☐	Radim Alisei
INC6	☐	Roche Cobas 6000 / 8000
INRCE	☐	Roche Cobas 4000 / e411
INEYS	☐	Roche Elecsys
INRME	☐	Roche Modular E170
INSAI	☐	Siemens Atellica IM
INCC	☐	Siemens/Bayer ACS 180
INCEN	☐	Siemens Centaur
INDPC	☐	Siemens/DPC Coat-a-count
INDPI	☐	Siemens/DPC Immulite 1000
INDP2	☐	Siemens/DPC Immulite 2000
INDP5	☐	Siemens/DPC Immulite 2500
INSF	☐	Stat Fax Elisa Readers
INTOS	☐	Tosoh AIA Series
INTOC	☐	Tosoh AIA-CL Series

Other methods, please specify on enrolment document

INSTRUMENT CODE	
REAGENT CODE	
OTHER UNITS, SPECIFY	

Osteocalcin ug/l

CODE		METHOD
OSTABC	☐	Autobio CLIA
OSTBRR	☐	Brahms Kryptor
OSTCIR	☐	CIS RIA
OSTLIA	☐	DiaSorin Liaison
OSTLIX	☐	DiaSorin Liaison XL
OSTDIA	☐	DiaSource ELISA
OSTDII	☐	DiaSource IRMA
OSTDRC	☐	DIRUI CM Series
OSTDRG	☐	DRG ELISA
OSTIDC	☐	IDS CLIA
OSTIDE	☐	ImmunoDiagnostic Systems ELISA
OSTMBE	☐	Metra Biosystems Inc. ELISA
OSTMVE	☐	MicroVue ELISA
OSTRCE	☐	Roche Cobas 4000 / e411
OSTC6	☐	Roche Cobas 6000 / 8000
OSTRME	☐	Roche Modular E170
OSTEYS	☐	Roche Elecsys
OSTDPI	☐	Siemens/DPC Immulite 1000
OSTDP2	☐	Siemens/DPC Immulite 2000/2500
OSTSNM	☐	SNIBE Maglumi analysers

Other methods, please specify on enrolment document

INSTRUMENT CODE	
REAGENT CODE	
OTHER UNITS, SPECIFY	

RQ9141 - IMMUNOASSAY SPECIALITY 1

METHOD QUESTIONNAIRE

Procalcitonin ug/l

CODE		METHOD
PCTAAI	☐	Abbott Alinity
PCTARC	☐	Abbott Architect
PCTABC	☐	Autobio CLIA
PCTSAN	☐	Beckman Acess PCT
PCTBDX9	☐	Beckman DxI 9000
PCTDXI	☐	Beckman DxI 600/800
PCTBHM	☐	Beijing Hotgen MQ60
PCTBIV	☐	bioMerieux Vidas
PCTBIZ	☐	Biozek PCT Fast Test
PCTBMI	☐	Boditech ichroma
PCTBRR	☐	Brahms Kryptor
PCTCDG	☐	CDG Q-Strip
PCTCAX	☐	Cormay Auryx ECLIA
PCTLIA	☐	DiaSorin Liaison
PCTLI2	☐	DiaSorin Liaison Brahms PCT II Gen
PCTLIX	☐	DiaSorin Liaison XL
PCTLX2	☐	DiaSorin Liaison XL Brahms PCT II Gen
PCTDIA	☐	Diazyme/Beckman PCT
PCTDRC	☐	DIRUI CM Series
PCTDRG	☐	DRG ELISA
PCTERT	☐	EDAN Rapid Test
PCTEYH	☐	ET Healthcare Pylon IRIS
PCTFIA	☐	Finecare FIA
PCTFJL	☐	Fujirebio Lumipulse G Series
PCTGFT	☐	Getein Fast Test Kit
PCTGF8	☐	Getein FIA8000 PCT

CODE		METHOD
PCTSLT	☐	Lifotronic eCL
PCTMAI	☐	Maccura I Series
PCTMIP	☐	Micropoint PCT
PCTMC2	☐	Mindray CL 8000i/6000i/2000i/1200i/1000i
PCTMC3	☐	Mindray CL900i
PCTNBT	☐	Norman Biological Technology PCT
PCTVEC	☐	Orthro Vitros 3600/5600/ECi/XT 7600
PCTRAD	☐	Radiometer AQT90 Flex
PCTRAB	☐	RayBiotech ELISA
PCTE8	☐	Roche Cobas e402/e801
PCTRCE	☐	Roche Elecsys/Cobas/Modular
PCTSIB	☐	Samsung IB Brahms PCT
PCTSIR	☐	Shanghai I - Reader
PCTSYI	☐	Shenzhen YHLO iFlash Series
PCTSAI	☐	Siemens Atellica IM 10995651
PCTSA2	☐	Siemens Atellica IM 11202699
PCTCEN	☐	Siemens Centaur 10378883
PCTCE2	☐	Siemens Centaur 11202697
PCTSLB	☐	Siemens Dimension EXL LOCI BRAHMS
PCTSNM	☐	SNIBE Maglumi analysers
PCTSNM2	☐	SNIBE Maglumi analysers II
PCTSP	☐	Stanbio PCT
PCTSLEC	☐	Shenzhen Lifotronic eCL8000 eCLIA
PCTSYU	☐	Shenzhen YHLO Unicell PCT
PCTWED	☐	Wuhan EasyDiagnosis

Other methods, please specify on enrolment document

INSTRUMENT CODE	
REAGENT CODE	
OTHER UNITS, SPECIFY	

Parathyroid Hormone (PTH) pmol/l

CODE		METHOD
PTHABC	☐	Autobio CLIA
PTHSAN	☐	Beckman Access/LXi725
PTHDXI	☐	Beckman DxI 600/800
PTHBLE	☐	Bioline ELISA
PTHBME	☐	Biomerica ELISA
PTHCIS	☐	CIS IRMA
PTHBYK	☐	DiaSorin IRMA
PTHLIAN	☐	DiaSorin Liaison N-TACT PTH II
PTHLIXN	☐	DiaSorin Liaison XL N-TACT PTH II
PTHDRG	☐	DRG ELISA
PTHDSI	☐	DSL IRMA
PTHFJL	☐	Fujirebio Lumipulse G Series
PTHIDS	☐	IDS-iSYS PTH
PTHSLT	☐	Lifotronic eCL
PTHMAI	☐	Maccura I Series
PTHMC2	☐	Mindray CL 8000i/6000i/2000i/1200i/1000i
PTHMC3	☐	Mindray CL9001
PTHVEC	☐	Ortho Vitros 3600/5600/ECi/XT 7600
PTHVEC2	☐	Ortho Vitros 3600/5600/ECi/XT 7600 PTH II
PTHRCE	☐	Roche Cobas 4000 / e411 PTH
PTHRCES	☐	Roche Cobas 4000 / e411 PTH STAT

CODE		METHOD
PTHC6	☐	Roche Cobas e601/602 PTH
PTHC6S	☐	Roche Cobas e601/602 PTH STAT
PTE8	☐	Roche Cobas e801 PTH
PTE8S	☐	Roche Cobas e801 PTH STAT
PTHEYS	☐	Roche Elecsys PTH
PTHEYSS	☐	Roche Elecsys PTH STAT
PTHRME	☐	Roche Modular E170 PTH
PTHRMES	☐	Roche Modular E170 PTH STAT
PTHSCR	☐	Scantibodies RIA
PTHSAI	☐	Siemens Atellica Solution
PTHCEN	☐	Siemens Centaur
PTHDPI	☐	Siemens/DPC Immulite 1000
PTHDP2	☐	Siemens/DPC Immulite 2000/2500
PTHSNM	☐	SNIBE Maglumi Analysers
PTHTOS	☐	Tosoh AIA Series
PTHTOC	☐	Tosoh AIA-CL Series

Other methods, please specify on enrolment document

INSTRUMENT CODE	
REAGENT CODE	
OTHER UNITS, SPECIFY	

Parathyroid Hormone (1-84) pmol/l

PTHARC	☐	Abbott Architect/Alinity Intact PTH
PTHBIV	☐	bioMerieux VIDAS PTH (1-84)
PTHC6B	☐	Roche Cobas e601/602 PTH (1-84)
PTE8B	☐	Roche Cobas e801 PTH (1-84)
PTHEYSB	☐	Roche Elecsys PTH (1-84)
PTHLIA	☐	DiaSorin Liaison 1-84 PTH
PTHLIX	☐	DiaSorin Liaison XL 1-84 PTH
PTHRCEB	☐	Roche Cobas 4000 / e411 PTH (1-84)
PTHRMEB	☐	Roche Modular E170 PTH (1-84)

Other methods, please specify on enrolment document

INSTRUMENT CODE	
REAGENT CODE	
OTHER UNITS, SPECIFY	

RQ9141 - IMMUNOASSAY SPECIALITY 1

METHOD QUESTIONNAIRE

1-25-(OH)2-Vitamin D pmol/l (PILOT)

CODE		METHOD
VDLIA	☐	DiaSorin Liaison
VDLIX	☐	DiaSorin Liaison XL
VDBYK	☐	DiaSorin RIA
VDDIE	☐	DIAsource, ELISA
VDDIR	☐	DIAsource RIA
VDHPLC	☐	HPLC
VDIDE	☐	IDS ELISA
VDIDS	☐	IDS iSYS
VDIDR	☐	IDS RIA
VDEYS	☐	Roche Elecsys

Other methods, please specify on enrolment document

INSTRUMENT CODE	
REAGENT CODE	
OTHER UNITS, SPECIFY	

25-OH-Vitamin D nmol/l

CODE		METHOD
VDARC	☐	Abbott Architect (3L52)
VDARC2	☐	Abbott Architect (5P02)/ Alinity (8P45)
VDAPI	☐	Applied Biosystems API 4000
VDAMI	☐	Agappe Mispa i3
VDAIC	☐	Aptasys Indra CLIA
VDABC	☐	Autobio CLIA
VDSAN	☐	Beckman Access 25 OH Vitamin D Total
VDDXI	☐	Beckman Dxl 600 / 800
VDBIO	☐	Biohit Total 25 OH Vitamin D
VDBIV	☐	bioMerieux Vidas/mini Vidas/Vidas 3
VDCIR	☐	Chongqing ISIA 25hydroxy vitD rapid test
VDCDG	☐	CDG Q-Strip
VDLIA	☐	DiaSorin Liaison
VDLIX	☐	DiaSorin Liaison XL
VDBYK	☐	DiaSorin RIA
VDDIE	☐	DIAsource ELISA
VDDIR	☐	DIAsource RIA
VDDIA	☐	Diazyme Vitamin D
VDDRC	☐	DIRUI CM Series
VDDRG	☐	DRG ELISA
VDEUE	☐	Euroimmune ELISA
VDFJL	☐	Fujirebio Lumipulse G Series
VDHP	☐	HPLC
VDHMC	☐	Human HumaCLIA SR
VDIBL	☐	IBL ELISA

CODE		METHOD
VDIDE	☐	IDS ELISA
VDIDS	☐	IDS iSYS
VDIDR	☐	IDS RIA
VDLM	☐	LC/MS
VDSLT	☐	Lifotronic eCL
VDMOE	☐	Monobind Inc. ELISA
VDMC2	☐	Mindray CL 8000i/6000i/2000i/1200i/1000i
VDMC3	☐	Mindray CL900i
VDORA	☐	Orgentec Alegria Elisa
VDVEC	☐	Ortho Vitros 3600/5600/ECi/XT 7600
VDEVE	☐	Randox Evolution
VDC6	☐	Roche Vitamin D Total
VDR2	☐	Roche Vitamin D Total II
VDE82	☐	Roche Vitmain D Total II e801
VDR3	☐	Roche Vitamin D Total III
VDE83	☐	Roche Vitmain D Total III e402/E803
VDSYI	☐	Shenzhen YHLO iFlash Series
VDSAI	☐	Siemens Atellica Solution
VDCEN	☐	Siemens Centaur
VDSDE	☐	Siemens Dimension EXL Vitamin D Total
VDSNM	☐	SNIBE Maglumi Analyser
VDTOS	☐	Tosoh AIA Series
VDTOC	☐	Tosoh AIA-CL Series
VDWXE	☐	Waters Quattro Premier XE
VDZYB	☐	Zybio CLIA

Other methods, please specify on enrolment document

INSTRUMENT CODE	
REAGENT CODE	
OTHER UNITS, SPECIFY	