REGISTRATION INSTRUCTIONS & RIQAS POLICIES

CRITERIA FOR PARTICIPATION

This programme is available to any laboratory running the Urine Toxicology (Drugs of Abuse) assays listed in this document. Qualitative (screening) and semi-quantitative (confirmatory) results will be accepted on this programme.

INTRODUCTION

Method questionnaires are available for all routine RIQAS Programmes and are reviewed and updated every month, as indicated by the issue date at the bottom of every page. They are designed to allow you to register for this RIQAS Programme and to inform you of RIQAS protocols and policies. It is important that you read and understand all the information in these introductory pages before completing the enrolment document, which forms the basis of your registration and contract with RIQAS. If you have any questions or concerns about any of the information presented in this document, please contact RIQAS either directly or through your local Randox Laboratories representative. RIQAS Calendar dates and information about the RIQAS portfolio of products can be found at www.randox.com/external-quality-assessment.

REGISTRATION INSTRUCTIONS

NOTE: IF A REGISTERED PARTICIPANT DOES NOT PARTICIPATE FOR A CYCLE, THEY WILL BE EXPECTED TO COMPLETE NEW ENROLMENT DOCUMENTS IN ORDER TO RE-JOIN THE PROGRAMME.

METHOD QUESTIONNAIRE:- To be retained by participant

This method questionnaire should be completed and retained by you for your records. Please ensure that you complete the method questionnaire in full. Your details will help us to classify your results correctly and thus provide you with useful statistical data.

In order to fully complete this questionnaire you will also need a copy of the RIQAS Instruments and Reagent Suppliers which is available to download from the Randox website (www.randox.com/external-quality-assessment). Please ensure you have this list available when completing this questionnaire.

Following this introduction section is the method questionnaire which indicates the method codes available for each parameter along with the standard RIQAS unit. On the method questionnaire, for each parameter you wish to run, please tick the method appropriate to you, then state your instrument code, reagent code, and the units that you use in your laboratory if they are different from the RIQAS standard units. If codes are not available for your assay, please state the details of your method clearly in the section at the end of the enrolment document.

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

ENROLMENT DOCUMENT:- To be returned to RIQAS

Please be aware that it may take up to 3 weeks to process enrolment documents if you are not entering your own assay details. When registering RIQAS enrolment documents, it is recommended that you state business contact details, rather than personal.

A. LABORATORY REFERENCE NUMBER

On receipt of an enrolment document, each participant is assigned a laboratory reference number which consists of a participant number which is unique to your laboratory and a registration letter which is assigned for each new registration we receive from you. If you are a current or previous participant, please state your participant number on the enrolment document. If you do not have a Laboratory Reference Number, this will be generated by RIQAS when you register for the first time. Please quote this number on all correspondence with RIQAS.

B. CYCLE/PRODUCT REQUIREMENTS

Please tick the cycles you wish to subscribe for. If there is more than one kit/product offered for the programme, please also tick the kit you wish to subscribe for.

C. PRIMARY CONTACT DETAILS

It is important to state the full address details of the Quality Assessment Officer or contact person who will receive all correspondence during the cycle. Please also state the company name of the Randox representative who is supplying you with the RIQAS product under 'Randox Office/Distributor' Please inform RIQAS of any change to contact details as soon as possible.

D. RIQASNet

RIQASNet is a web-based online method for result entry / method changes and additions of parameters / viewing of released reports. To access RIQASnet go to www.riqas.net. Internet access and login details are required for RIQASNet and Adobe Reader is required for viewing reports. Your initial login information and password will be supplied by RIQAS. Once you have logged in for the first time you will be able to change your RIQASNet password. If you forget your password please follow the 'Forgotten Password' link. Your login information will be based on the 1st email address you supply on your enrolment document. A PDF copy of the report will be sent to this address and can also be sent to 2 other email addresses. These addresses should be stated on your enrolment document.

E. PDF REPORTS

Reports are sent as PDF files. These files can be sent to up to 3 email addresses. Adobe Reader is required to view the reports. The email addresses to which reports are sent can be reviewed and changed on RIQASNet.

F. CUSTOMER DECLARATION

The declaration indicates that by submitting your enrolment document to RIQAS, either directly or via your local Randox representative, you have read and understood the RIQAS policies stated in the most recent Method Questionnaire associated with this programme. You understand that the submission of your enrolment document to RIQAS marks the beginning of an on-going agreement, and you will be automatically enrolled in subsequent cycles of this programme until we receive written confirmation of your cancellation. This should be received 12 weeks prior to the month in which the cycle starts. You understand that you must inform RIQAS of any changes to your contact details, assay details or contract status. You authorise Randox Laboratories Ltd. to send communication related to the products and service provided to the e-mail or postal addresses stated on your submitted enrolment document. You understand that you are permitted to request disclosure of, change or erase personal details held by Randox Laboratories Ltd. at any time. Note: Method questionnaires are updated every month and the issue date is stated on every questionnaire and enrolment document.

G. REGISTRATION OF ASSAY DETAILS

Labs can register their assay details using RIQASNet or can complete the 'Registration of Assay Details' section of the enrolment document. Labs should tick the appropriate box under the 'Registration of Assay Details' section of the enrolment document. If a lab wishes RIQAS to register their assay details, they should complete the Registration of Assay Details section using the codes from this method questionnaire and the Instrument/Reagent Supplier Book.

Once a participant has registered they will receive an email containing their RIQASNet login information. Once you have successfully logged in to RIQASNet you will see your various laboratory reference numbers for each registered programme. If you have opted to add parameters/assay details using RIQASNet, please do so as soon as possible (see below).

If no code is available for your assay, please state the details of your method clearly in the section at the end of the enrolment document or follow the instructions on RIQASNet.

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 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 Scherre Co-ordinator: Sally Picton

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

Creatinine - umol/l		
CODEMETHODCREAP CRDEPAlkaline picrate no deprot. Alkaline picrate with deprot. Creatinine PAP method Enzymatic UV method CREUVCreatinine PAP method Enzymatic UV method Enzymatic UV method Enzymatic UV method Enzymatic UV method CREND CREAD CREADJaffe rate blanked Other Dry Chemistry Other enzymatic methods CREAD CREDT CREIDOther enzymatic methods CREAD Utiros, DT60/DT60 II/DTSC II Vitros, IDMS traceableINSTRUMENT CODEImage: Complexity of the second		
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Amphetamine Group - ng/ml CODE METHOD AM1CD CEDIA AM1CL Chemiluminescence AM1CB Competitive Antibody Binding AM1CB DRI-EIA AM1EL ELISA AM1EP EMIT AM1FP FPIA AM1HR HRMS AM1PC Point of Care AM1TG Quidel Triage AM1RX Randox Biochip Array Technology	ology	
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d- Amphetamine - ng/ml		
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d- Methamphetamine - ng/ml		
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MDMA - ng/ml		
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	REAGENT SUPPLIER CODE	
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OTHER UNITS, SPECIFY		

METHOD QUESTIONNAIRE		
Phenobarbital - ng/ml		
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Benzodiazepines Group - ng	/ml	
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INSTRUMENT CODE	REAGENT SUPPLIER CODE	
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OTHER UNITS, SPECIFY		

Lorazepam - ng/ml		
CODE METHOD BELCD CEDIA BELCL Chemiluminescence BELCB Competitive Antibody Binding BELDR DRI-EIA BELEL ELISA BELEH EMIT BELEP EMIT BELEP FPIA BELGC GC BELGH GC/MS BELHP HPLC BELHR HRMS BELLM LC/MS BELPC Point of Care BELTG Quidel Triage BELRX Randox Biochip Array Technol	ology	
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Oxazepam - ng/ml		
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Cannabinoids Group - ng/ml		
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RQ9139 - URINE TOXICOLOGY PROGRAMME METHOD QUESTIONNAIRE

11-NOR-D-9-THC-9-COOH - ng/ml CODE METHOD CATCD CEDIA CATCL Chemiluminescence CATCB Competitive Antibody Binding CATDR DRI-EIA CATEL ELISA CATEM EMIT CATEP EMIT II+ CATFP FPIA CATHR HRMS CATKM KIMS CATPC Point of Care CATTG Quidel Triage CATRX Randox Biochip Array Technology CATTL TLC INSTRUMENT CODE REAGENT SUPPLIER CODE CUT OFF VALUE CROSS REACTIVITY FACTOR OTHER UNITS, SPECIFY Cocaine Group - ng/ml CODE METHOD CO1CD CEDIA CO1CL Chemiluminescence CO1CB Competitive Antibody Binding CO1DR DRI-EIA CO1EL ELISA CO1EM EMIT CO1EP EMIT II+ CO1FP FPIA CO1HR HMRS CO1KM KIMS CO1PC Point of Care CO1TG Quidel Triage CO1RX Randox Biochip Array Technology INSTRUMENT CODE REAGENT SUPPLIER CODE CUT OFF VALUE CROSS REACTIVITY FACTOR OTHER UNITS, SPECIFY Benzoylecgonine - ng/ml CODE METHOD COBCD CEDIA COBCL Chemiluminescence Competitive Antibody Binding COBCB COBDR DRI-EIA COBEL ELISA COBEM EMIT COBEP EMIT II+ COBFP FPIA COBHR HRMS COBKM KIMS COBPC Point of Care COBTG Quidel Triage Randox Biochip Array Technology COBRX INSTRUMENT CODE REAGENT SUPPLIER CODE CUT OFF VALUE CROSS REACTIVITY FACTOR OTHER UNITS, SPECIFY

Cotinine - ng/ml		
CODE METHOD		
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OTHER UNITS, SPECIFY		
Ethanol Group - mg/dl		
CODE METHOD ETREA Axsym - REA ET1CD CEDIA ET1CL Chemiluminescence ET1CB Competitive Antibody Bindin ET1CB DRI-EIA ET1EL ELISA ET1EL EMIT ET1EZ Enzymatic Method ET1FP FPIA ETIGC GC ET1TG Quidel Triage ET1RX Randox Biochip Array Techn INSTRUMENT CODE CUT OFF VALUE OTHER UNITS, SPECIFY	-	
LSD - ng/ml		
CODE METHOD LS1CD CEDIA LS1CL Chemiluminescence LS1CB Competitive Antibody Bindir LS1CB DRI-EIA LS1EL ELISA LS1EP EMIT LS1FP FPIA LS1HR HRMS LS1KM KIMS LS1TG Quidel Triage LS1TG Quidel Triage	-	
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OTHER UNITS, SPECIFY		

ethadone - ng/ml
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DDP - ng/ml
DE METHOD ECD CEDIA Chemiluminescence Competitive Antibody Binding ECB DRI-EIA EEB ELISA EEEH EMIT EEEP EMIT II+ EEFP FPIA EERK HRMS EERK LC/MS EEPC Point of Care Quidel Triage Randox Biochip Array Technology STRUMENT CODE REAGENT SUPPLIER CODE TOFF VALUE CROSS REACTIVITY FACTOR
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CODE	METHOD
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	Chemiluminescence Competitive Antibody Binding
OPBOR	DRI-EIA
OPBEL	
OPBEM	EMIT
OPBEP	
OPBFP OPBHR	FPIA HRMS
ОРВКМ	KIMS
OPBPC	Point of Care
OPBTG	Quidel Triage
OPBRX OPBTL	Randox Biochip Array Technology TLC
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INSTRUMENT (CODE REAGENT SUPPLIER CODE
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OTHER UNITS,	SPECIFY
Free Morp	phine - ng/ml
CODE	METHOD
OPFCD	CEDIA
OPFCL	Chemiluminescence
OPFCB	Competitive Antibody Binding
OPFDR	DRI-EIA
OPFEL OPFEM	ELISA EMIT
OPFEP	EMIT II+
OPFFP	FPIA
OPFHR	HRMS
OPFKM OPFPC	KIMS Deint of Core
OPFTG	Point of Care Quidel Triage
OPFRX	Randox Biochip Array Technology
OPFTL	TLC
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OTHER UNITS,	
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Phencycli	dine - ng/ml
CODE	METHOD
PE1CD	CEDIA
PE1CL	Chemiluminescence
PE1CB	Competitive Antibody Binding
PE1DR PE1EL	DRI-EIA ELISA
PE1EM	
PE1EP	EMIT II+
PE1FP	FPIA UPMC
PE1HR PE1KM	HRMS KIMS
PE1PC	Point of Care
PE1TG	Quidel Triage
PE1RX	Randox Biochip Array Technology
INSTRUMENT (CODE REAGENT SUPPLIER CODE
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OTHER UNITS,	SPECIFY

Propoxyphene Group - ng/	ml	
CODE METHOD		
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PR1DR DRI-EIA		
PR1EL ELISA		
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OTHER UNITS, SPECIFY]	
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CODE METHOD		
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PRNDR DRI-EIA		
PRNEM EMIT PRNEP EMIT II+		
PRNFP FPIA		
PRNHR HRMS		
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OTHER UNITS, SPECIFY	1	
TCA Group - ng/ml	-	
TCA Group - ng/ml		
TCA Group - ng/ml CODE METHOD TC1CD CEDIA		
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