ERNDiM

Quality Assurance in Laboratory Testing for IEM

EQA Schemes Catalogue and Participant Guide 2022

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European Research Network for evaluation and improvement of screening, Diagnosis and treatment of Inherited disorders of Metabolism

Contents

Version Date	Amendments
22 September 2021	• 2022 EQA Catalogue published
15 November 2021	• Administration Office phone number corrected to +44 161 757 4952 • Country EQA samples will be dispatched from, added to EQA schemes' summary tables on pages 7, 10 and 13

1. Introduction

ERNDIM is an independent not-for-profit foundation which has been providing External Quality Assurance (EQA) schemes in the field of inborn errors of metabolism since 1994. While originally a European organisation we now have over 400 participants from 62 countries, with approximately 60% of our participants coming from outside of Europe in 2021.

In 2022 we will be operating 16 EQA schemes which are developed & monitored by a Scientific Advisory Board comprising 21 leading scientists from 9 countries. You can find full details of the EQA schemes in section 2 (pages 4 to 13) and details of how to register to participate in the 2022 schemes in section 5 (pages 16 to 21).

The Participants' Guide on pages 16 to 21 includes information on all aspects of EQA scheme participation, including how to register, the use of EQA data in publications and how to pay your invoices. If you need further information for any of the items mentioned in the Participants' Guide please contact admin@erndim.org.

The terms and conditions of EQA Scheme Participation for Participating Centres can be found on pages 22 to 23. Please make sure that you read and understand these. When the primary contact for your centre logs into the ERNDIM Registration Website for the first time, after registration for the 2022 EQA schemes has opened, they will need to accept these terms and conditions before they will be able to submit their EQA order. If you have any questions about the terms and conditions, please contact admin@erndim.org.

2. EQA Schemes

2.1. Quantitative EQA Schemes

The main purpose of the quantitative schemes is to evaluate the ability of the participating laboratories to quantitatively analyse the concentrations of the analytes included in each scheme.

Details of the analytes included in each Quantitative scheme are below and full details of the scheme design (number of samples, submission deadlines, subcontracted activities etc.) are given in section 2.1.1 on page 7.

Cluster Labs

Each participating laboratory must produce its own results and cannot send samples to a subcontracted or cluster laboratory. **The use of cluster laboratories is therefore not allowed in any of the Quantitative schemes.**

Acylcarnitines in serum† — Scheme Code: ACS

Aim: Comparison of Acylcarnitines analysis in a lab with respect to median and target values

Status: Operating as a separate full EQA scheme since 2017; some acylcarnitines were previously included in the Special Assays in serum scheme

Analytes (2022):

3-OH- Butyrylcarnitine (C4-OH)	Hexanoylcarnitine (C6)
3-OH-Isovalerylcarnitine (C5-OH)	Isovalerylcarnitine (C5)
3-OH- Palmitoylcarnitine (C16-OH)	Malonylcarnitine (C3-DC)
3-OH-Stearoylcarnitine (C18-OH)	Methylmalonylcarnitine (C4-DC)
Acetylcarnitine (C2)	Octanoylcarnitine (C8)
Butyrylcarnitine (C4)	Oleoylcarnitine (C18:1)
Cis-5-Tetradecenoylcarnitine (C14:1)	Palmitoylcarnitine (C16)
Decanoylcarnitine (C10)	Propionylcarnitine (C3)
Dodecanoylcarnitine (C12:0)	Stearoylcarnitine (C18)
Free Carnitine (C0)	Tiglylcarnitine (C5:1)
Glutarylcarnitine (C5-DC)	Total Carnitine

Scientific Advisor: Dr Pedro Ruiz-Sala, admin@erndim.org

Scheme Organiser: MCA†

Purines and Pyrimidines (urine)† — Scheme Code: PPU

Aim: Comparison of Purine and Pyrimidine analysis in a lab with respect to median and target values

Status: Full ERNDIM EQA scheme since 2000

Analytes (2022):

5-OH Methyluracil	Deoxy-uridine	Succinyl adenosine[2]
Adenine	Dihydro-thymine	Thymidine
Adenosine	Dihydro-uracil	Thymine
AICAriboside	Guanosine	Uracil
Creatinine (mmol/L)[1]	Hypoxanthine	Uric acid[1]
Cytidine	Inosine	Uridine
Deoxy-adenosine	Orotic acid	Xanthine
Deoxy-guanosine	Orotidine	
Deoxy-inosine	Pseudo-uridine	

[1] *These analytes are present in the matrix so results can be recorded for comparison between labs BUT the concentrations do not vary and they are not included in the Individual Online Annual Reports or Certificates of participation*

[2] *Succinyl adenosine is present at two concentrations only in 2022*

Scientific Advisor: Dr Jörgen Bierau, admin@erndim.org

Scheme Organiser: MCA†

† *Full details of the scheme design (number of samples, submission deadlines, subcontracted activities etc.) for each of the Quantitative schemes are given in section 2.1.1 on page 7.*

Quantitative Amino Acids (serum)† — Scheme Code: QTAS

Aim: Comparison of Amino Acid analysis in a lab with respect to median and target values

Status: Full ERNDIM EQA scheme since 1993

Analytes[3] (2022):

2-Aminobutyric acid	Cystathionine[3]	Leucine	Sarcosine
Alanine	Cystine	Lysine	Serine
Allo-isoleucine	Glutamic acid	Methionine	Sulphocystine
Arginine	Glutamine	Ornithine	Taurine
Arginino succinic acid	Glycine	Phenylalanine	Tele-Methylhistidine
Asparagine	Histidine	Pipecolic acid[3]	Threonine
Aspartic acid	Homocitrulline	Proline	Tryptophan[3]
Aspartyl glucosamine[3]	Hydroxyproline	Pros-methylhistidine	Tyrosine
Citrulline	Isoleucine	Saccharopine[3]	Valine

[3] Please note, there is a core panel of amino acids which are included every year, but other special amino acids may vary from year to year for example, those marked with [3]

Scientific Advisor: Dr Rachel Carling, admin@erndim.org

Scheme Organiser: MCA†

Quantitative Organic Acids (urine)† — Scheme Code: QTOU

Aim: Comparison of Organic Acid analysis in a lab with respect to median and target values

Status: Full ERNDIM EQA scheme since 1993

Analytes (2022):

2-Methylcitric acid	4-OH-Butyric acid	Methylmalonic acid
2-OH-Glutaric acid	Adipic acid	Mevalonic acid
3-Methylglutaconic acid	Creatinine (mmol/L)[4]	N-acetylaspartic acid
3-Methylglutaric acid	Ethylmalonic acid	Pyro glutamic acid
3-OH-3-Methylglutaric acid	Fumaric acid	Sebacic acid
3-OH-Butyric acid	Glutaric acid	Suberic acid
3-OH-Glutaric acid	Hexanoylglycine	Suberylglycine
3-OH-Isovaleric acid	Isovalerylglycine	Tiglylglycine
3-OH-Propionic acid	Keto-glutaric acid	Vanillactic acid

[4] This analyte is present in the matrix so results can be recorded for comparison between labs BUT the concentration does not vary, and it is not included in the Individual Online Annual Reports or Certificates of participation

Scientific Advisor: Mme Clothilde Roux, admin@erndim.org

Scheme Organiser: MCA†

Special Assays in dried blood spots† — Scheme Code: SADB

Aim: To educate and assess the ability of laboratories to analyse analyte levels in dried blood spots (DBS)

Status: Pilot scheme 2017-2018, operating as a full scheme for the first time in 2019

No. of samples/year: 8 EQA samples and 8 additional DBS

N.B. The results submitted for the additional DBS will be for internal ERNDIM use and will not count towards overall performance evaluations

Analytes (2022):

([5] the inclusion of NTBC is sponsored by SOBI)

Allo isoleucine	Methionine	Tyrosine
Isoleucine	NTBC[5] (nitisone)	Valine
Leucine	Phenylalanine	C0 free carnitine
L-Homocysteine	Succinylacetone	

Scientific Advisor: Dr Rachel Carling, admin@erndim.org

Scheme Organiser: MCA†

† Full details of the scheme design (number of samples, submission deadlines, subcontracted activities etc.) for each of the Quantitative schemes are given in section 2.1.1 on page 7.

Special Assays in Serum† — Scheme Code: SAS

Aim: Comparison of outcome in heterogeneous group of lab-assays, relevant to the diagnosis of inborn errors of metabolism, in respect to median and target values. In addition, recovery of added analyte, precision, and analytical linearity are tested

Status: Full ERNDIM EQA scheme since 1993

Analytes (2022):

3 OH Butyrate	Cholestanol	L-Pipecolic acid
7-Dehydrocholesterol	Cholesterol[6]	Lyso-Gb3
7-Ketocholesterol	Coenzyme Q10	Lysosphingomyeline
Biotinidase[6]	Creatine	Methylmalonic acid
C22:0 Behenic acid	Galactose	NEFA[6]
C24:0 Lignoceric acid	Glycosylsphingosine	Phytanic acid
C26:0 Cerotic acid	Guanidine acetic acid	Pristanic acid
Carnitine Free	Homocysteine	Pyruvic acid
Cholestane-3β,5α,6β-triol	Lactic acid	Succinylacetone

[6] *These analytes are present in the matrix so results can be recorded for comparison between labs BUT the concentrations do not vary, and they are not included in the Individual Online Annual Reports or Certificates of participation*

Scientific Advisor: Dr Rafael Artuch, admin@erndim.org

Scheme Organiser: MCA†

Special Assays in Urine† — Scheme Code: SAU

Aim: Comparison of outcome of a heterogeneous group of lab-assays, relevant to the diagnosis of inborn errors of metabolism, in respect to median and target values. In addition, recovery of added analyte, precision and analytical linearity are tested

Status: Full ERNDIM EQA scheme since 1993

Analytes (2022):

4-OH-Glutamic acid	Glycolic Acid	L-Pipecolic acid
5-Aminolevulinic acid	Guanidinoacetate	Orotic acid
5-OH-Indolacetic acid	Homocitrulline	Oxalic acid
Carnitine Free	Homogentisic acid	Sialic acid
Creatine	Homovanillic acid	Succinylacetone
Creatinine	Lactic acid	Sulphocysteine
D,L-Glyceric acid	L-Cystine	
Galactitol	Mucopolysaccharides (Chondroitin sulfate)	

Scientific Advisor: Dr Rafael Artuch, admin@erndim.org

Scheme Organiser: MCA†

Special Assays Combined — Scheme Code: SAC

If you wish to order both the Special Assays in Serum and Special Assays in Urine scheme please select 'Special Assays Combined (serum + urine)' when submitting your order on the registration website and a discount for ordering both schemes will be applied to your order (see the EQA scheme price list on page 15).

† *Full details of the scheme design (number of samples, submission deadlines, subcontracted activities etc.) for each of the Quantitative schemes are given in section 2.1.1 on page 7.*

2.1.1. Quantitative EQA Schemes' summary

Full detail of the analytes included in each scheme can be found on pages 4 to 6.

	ACS	PPU	QTAS	QTOU	SADB	SAS	SAU
Detailed scheme information on page:	p4	p4	p5	p5	p5	p6	p6
General							
Eligibility Requirements:	Participants must produce their own results and cannot send samples to a sub-contracted (or cluster) laboratory						
Use of cluster labs allowed?	No	No	No	No	No	No	No
No. of registrations (2021):	127	50	269	131	100	253	201
Geographic area:	Worldwide						
Sample volume/vial	0.5ml	2.5ml	1ml	5ml	75 µl initial blood volume	5ml	5ml
Matrix of human origin, spiked with commercially available analytes	Yes						
Matrix:							
Dried blood spots					Yes		
Lyophilised plasma/serum	Yes		Yes			Yes	
Lyophilised urine		Yes		Yes			Yes
Scheme Design							
Sample design/selection:	Scientific Advisor for each scheme						
Sample manufacture subcontracted to:	MCA						
Sample aliquoting subcontracted to:	MCA						
Sample Dispatch subcontracted to:	MCA: one dispatch per year						
Country samples will be dispatched from:	Netherlands						
No of samples/year:	8				8 EQA samples and 8 additional DBS[7]	8	
Results Submissions							
No of submission deadlines/year:	8						
Submission of results:	online (ERNDIM-MCA website)						
Scoring of results:							
Analysis scored	Yes						
Reports:							
Interim Reports							
Published 14 days after each submission deadline	Yes						
Individual Lab Annual Reports							
Published 14 days after the last submission deadline	Yes						
Full anonymised scheme results included in AR	No						
Scheme Annual Reports (AR)	published in Jan-Feb of the following year						

[7] = see SADB scheme information on page 5

[†] Full details of the scheme design (number of samples, submission deadlines, subcontracted activities etc.) for each of the Quantitative schemes are given in section 2.1.1 on page 7.

2.2. Hybrid EQA Schemes

The main purposes of the hybrid schemes are to evaluate the ability of the participating laboratories to: 1) quantitatively analyse the concentrations of the analytes included in each scheme; **and** 2) establish or exclude a specific diagnosis of an inherited metabolic disease (IMD).

Details of the analytes included in each Hybrid scheme are below and full details of the scheme design (number of samples, submission deadlines, subcontracted activities etc.) are given in section 2.2.1 on page 10.

Cluster Labs

Each participating laboratory must produce its own results and cannot send samples to a subcontracted or cluster laboratory. **The use of cluster laboratories is therefore not allowed in any of the Hybrid schemes.**

Cystine in White Blood Cells[††] — Scheme Code: CWBC

Aim: Comparison of analysis of Cystine in White Blood Cells (WBC)

Status: Full ERNDIM EQA scheme since 2005

No. of samples/year: 8 pairs of protein and WBC supernatants

Volume/sample: Pellet and supernatant equivalent to extracts from 5 ml whole blood samples

Sample matrix: Protein is lyophilised, WBC supernatants are liquid

Analytes (2022): Cystine (nmol/aliquot) (250 µL SNT sample)
Protein(mg/pellet) (PP sample)
Cystine (nmol 1/2 cys/mg protein, calculated as if isolated from one 5 mL blood sample)

Scientific Advisor: Dr Daniel Herrera, admin@erndim.org

Scheme Organiser: MCA[††]

Lysosomal Enzymes (fibroblasts)[††] — Scheme Code: LEFB

Aim: Testing of reproducibility and ability to detect enzyme deficiencies in Lysosomal storage disorders

Status: Full ERNDIM EQA scheme since 2011 (ran as a pilot scheme 2006 – 2010)

Expected Analytes (2022):

- Alpha-Galactosidase
- Alpha-Glucosidase
- Alpha-Iduronidase
- Aspartylglucosaminidase
- Beta-Galactosidase
- Beta-Glucosidase
- Hexosaminidase A + B
- Hexosaminidase A
- Galactosyceramidase
- Sphingomyelinase
- Protein

Please note, as these are clinical samples enzymes may vary depending on the availability of samples

Scientific Advisor: Ms Marie Jackson, admin@erndim.org

Scheme Organiser: MCA[††]

Neurotransmitters in cerebrospinal fluid (CSF)[††] — Scheme Code: NCSF

Aim: To educate and assess the ability of laboratories to diagnose inborn errors of neurotransmitter metabolism

Status: Pilot scheme 2014-2015, full scheme from 2016

Analytes (2022):

- 3-methyl dopa (3-MD)
- 5-hydroxyindoleacetic acid (5-HIAA)
- 5-OH-Tryptophan (5-HTTP)
- Homovanillic acid (HVA)
- HVA:5-HIAA ratio

Scientific Advisor: Dr Simon Pope, admin@erndim.org

Scheme Organiser: MCA[††]

[††] Full details of the scheme design (number of samples, submission deadlines, subcontracted activities etc.) for each of the Hybrid schemes are given in section 2.2.1 on page 10.

Pterins in Urine[††] — Scheme Code: PTU

Aim: To educate and assess the ability of laboratories to diagnose inborn errors of tetrahydrobiopterin (BH_4) metabolism

Status: Pilot scheme 2014-2016, operating as a full scheme since 2017

Analytes (2022):
- Creatinine (mmol/L)
- Biopterin (µmol/L & mmol/mol Creat)
- Neopterin (µmol/L & mmol/mol Creat)
- Primapterin (µmol/L & mmol/mol Creat)

Scientific Advisor: Dr Alessio Cremonesi, admin@erndim.org

Scheme Organiser: MCA[††]

[††] Full details of the scheme design (number of samples, submission deadlines, subcontracted activities etc.) for each of the Hybrid schemes are given in section 2.2.1 on page 10.

2.2.1. Hybrid EQA Schemes' summary

Full detail of the analytes included in each scheme can be found on pages 8 to 9.

	CWBC	LEFB	NCSF	PTU
Detailed scheme information on page:	p8	p8	p8	p9
General				
Eligibility Requirements:	Participants must produce their own results and cannot send samples to a sub-contracted (or cluster) laboratory			
Use of cluster labs allowed?	No			
No. of registrations (2021):	37	72	38	35
Geographic area:	Worldwide			
EQA Samples				
Sample volume/vial	5ml[8]	0.5 mg lyophilised protein	0.5ml	1ml
Sample type				
Artificial/human matrix spiked with commercially available analytes			Yes	
Clinical samples		Yes		
Matrix of human origin, spiked with commercially available analytes	Yes			Yes
Matrix:				
Lyophilised cerebrospinal fluid			Yes	
Lyophilised fibroblasts		Yes		
Lyophilised urine				Yes
White blood cells*	Yes[8]			
Scheme Design				
Sample design/selection:	Scientific Advisor for each scheme			
Sample manufacture subcontracted to:	MCA	CHU Lyon	MCA	
Sample aliquoting subcontracted to:	MCA			
Sample Dispatch subcontracted to:	MCA: one dispatch per year			
Country samples will be dispatched from:	Netherlands			
No of samples/year:	8[8]	6	8	
Results Submissions				
No of submission deadlines/year:	8	2	8	8
Submission of results:	online (ERNDIM-MCA website)			
Quantitative results submission is mandatory	Yes	Yes	Yes	Yes
Interpretation results submission is mandatory	No	Yes	No	No
Scoring of results:				
Analysis scored	Yes			
Diagnoses Scored	Yes	Yes	Yes	Yes
Reports:				
Interim Reports				
Published 14 days after each submission deadline	Yes			
Individual Lab Annual Reports				
Published 14 days after the last submission deadline	Yes	No	Yes	Yes
Full anonymised scheme results included in AR	-	Yes	-	-
Scheme Annual Reports (AR)	published in Jan-Feb of the following year			

[8] = see CWBC scheme information on page 8

2.3. Qualitative EQA Schemes

The main purpose of the Qualitative schemes is to evaluate the ability of the laboratory to establish or exclude a specific diagnosis of an inherited metabolic disease (IMD). Participants are expected to obtain correct analytical results, to recognize the characteristic diagnostic patterns, to make a diagnostic conclusion and to suggest additional test(s) necessary to confirm the diagnosis. These schemes use clinical samples as the EQA materials.

Details of the analyte groups included in each Qualitative scheme are below and full details of the scheme design (number of samples, submission deadlines, subcontracted activities etc.) are given in section 2.3.1 on page 13.

When schemes are organised by more than one centre, participants will be assigned to a centre by the Administration Office.

Sample Donations

For the Qualitative schemes, a 20% discount on the scheme price is available to participants that donated a sample that was used as an EQA material in the previous scheme year. The Admin Office will automatically add this discount to the invoices for qualifying laboratories after the order has been submitted. For more details please contact admin@erndim.org.

Cluster Labs

For all Qualitative schemes, except the DPT scheme, each participating laboratory must produce its own results and cannot send samples to a subcontracted laboratory. **The use of cluster laboratories is therefore not allowed in any of the Qualitative schemes, except for the DPT scheme, and participating laboratories must carry out both the analysis and interpretation of the EQA samples.**

Acylcarnitines in dried blood spots††† — Scheme Code: ACDB

Aim: To educate and assess the ability of laboratories to detect inherited disorders resulting in recognisable whole blood acylcarnitine profiles

Status: Operated since 2003 (London only). In 2010 and 2017 additional centres in Heidelberg and Zurich, respectively were added due to increasing participant numbers. In 2018 Rome replaced Zurich as the third centre.

Eligibility Requirements: Participating laboratories must carry out both the analysis **and** interpretation of the EQA samples. **The use of cluster laboratories is not allowed.**

Analytes: Dependent upon disorder

Scientific Advisors: London: Dr Charles Turner, admin@erndim.org
Heidelberg: Dr Joachim Janda, admin@erndim.orge
Rome: Dr Cristiano Rizzo, admin@erndim.org

Scheme Organisers: CSCQ†††

Congenital Disorders of Glycosylation (plasma/serum)††† — Scheme Code: CDG

Aim: Qualitative interpretation of sialotransferrin profiles in the screening for Congenital Disorders of Glycosylation (CDG)

Status: Full ERNDIM EQA scheme since 2010 (ran as a pilot scheme in 2008 & 2009)

Eligibility Requirements: Participating laboratories must carry out both the analysis **and** interpretation of the EQA samples. **The use of cluster laboratories is not allowed.**

Volume/sample: 25 microlitres
(If you require extra sample volume in order to carry out the analysis, a maximum of 2 extra sample sets per participant can be purchased at a discounted price, however please note that availability is limited due to the nature of the EQA materials. Please contact admin@erndim.org if you would like further details.)

Analytes: Sialotransferrin isoforms

Scientific Advisor: Dr Dulce Quelhas, admin@erndim.org

Scheme Organiser: MCA and CSCQ†††

††† Full details of the scheme design (number of samples, submission deadlines, subcontracted activities etc.) for each of the Hybrid schemes are given in section 2.3.1 on page 13.

Diagnostic Proficiency Testing (urine)††† — Scheme Code: DPT

Aim: To assess test selection, analysis, interpretation and advice in the performance of tests related to the detection of inherited metabolic disorders

Status: Operated since 1990 (Netherlands only). In 1998 a further 3 organising centres were added (Czech Republic, France and UK) and in 2006 a fifth centre (Switzerland) was added as part of the EuroGentest project. [Each organising centre focuses on a separate geographic area]

Eligibility Requirements: **Any urine sample can be sent that a laboratory operating to expected standards would be able to diagnose, but participants should be able to perform this core panel of tests:** amino acids, organic acids, oligosaccharides, mucopolysaccharides, purines & pyrimidines. If your laboratory does not offer this core panel of tests it may not be possible to obtain satisfactory performance and we strongly recommend that you do not register for the DPT scheme. *The use of cluster labs, for instance for purines & pyrimidines, is acceptable but the participant lab is responsible for the results submitted.*

Analytes: Dependent upon disorder

Scientific Advisors: Czech Republic: Mr Petr Chrastina, admin@erndim.org
France: Dr Christine Vianey-Saban, admin@erndim.org
Netherlands: Dr George Ruijter, admin@erndim.org
Switzerland: Dr Déborah Mathis, admin@erndim.org
UK: Mrs Joanne Croft, admin@erndim.org

Scheme Organiser: CSCQ†††

Qualitative Organic Acids (urine)††† — Scheme Code: QLOU

Aim: To educate and assess the ability of laboratories to detect inherited disorders resulting in recognisable patterns of organic acid excretion

Status: Operated since 1992 (Sheffield only), with additional centres in Heidelberg and Barcelona added in 2002 and 2018, respectively, due to increased participant numbers.

Eligibility Requirements: Participating laboratories must carry out both the analysis **and** interpretation of the EQA samples. **The use of cluster laboratories is not allowed.**

Analytes: Dependent upon disorder

Scientific Advisors: Barcelona: Dr Judit Garcia-Villoria, admin@erndim.org
Sheffield: Mrs Camilla Scott, admin@erndim.org
Heidelberg: Dr Joachim Janda, admin@erndim.org

Scheme Organiser: CSCQ†††

Urine Mucopolysaccharides††† — Scheme Code: UMPS

Aim: To educate and assess the ability of laboratories to detect mucopolysaccharidoses

Status: Pilot scheme in 2010 & 2011, full scheme from 2012

Eligibility Requirements: Participating laboratories must carry out both the analysis **and** interpretation of the EQA samples. **The use of cluster laboratories is not allowed.**

Analytes: Quantitative (related to creatinine) and qualitative analysis of mucopolysaccharides with interpretation of results obtained

Scientific Advisor: Dr Berthil Prinsen, admin@erndim.org

Scheme Organiser: MCA and CSCQ†††

††† Full details of the scheme design (number of samples, submission deadlines, subcontracted activities etc.) for each of the Hybrid schemes are given in section 2.3.1 on page 13.

2.3.1. Qualitative EQA Schemes' Design summary

Full detail of the analyte groups included in each scheme can be found on pages 11 to 12.

	DPT	ACDB	CDG	QLOU	UMPS
Detailed scheme information on page:	p12	p11	p11	p12	p12
General					
Method Orientated scheme?	No	Yes			
Eligibility Requirements:	See DPT information on p12	Participants must produce their own results and cannot send samples to a sub-contracted (or cluster) laboratory			
Use of cluster labs allowed?	Yes	No			
No of organising centres:	5	3	1	3	1
No. of registrations (2021):	102 (19-21 per centre)	133 (44-45 per centre)	67	224 (74-75 per centre)	89
Geographic area:	Worldwide				
EQA Samples					
Sample volume/vial:	5-10ml	30-50µl	25 µl[9]	2-3 ml/vial	5ml
Sample type	Clinical samples				
Matrix:					
Dried Blood Spots on S&S903 filter paper		Yes			
Heat treated urine	Yes			Yes	
Lyophilised plasma/serum			Yes		
Lyophilised urine					Yes
Scheme Design					
Sample design/selection	Scientific Advisors (SA) for each scheme				
Sample aliquoting subcontracted to:	CSCQ	SA	MCA	CSCQ	MCA
Sample Dispatch subcontracted to: (one dispatch per year)	CSCQ	CSCQ	MCA	CSCQ	MCA
Country samples will be dispatched from:	Switzerland	Switzerland	Netherlands	Switzerland	Netherlands
No of samples/year	6				
Results Submissions					
No of submission deadlines/year	2				
Submission of results	Online (ERNDIM-CSCQ website)				
Scoring of results:					
Analysis	Yes				
Interpretation, including diagnoses	Yes				
Reports:					
Interim Reports					
Published 8-10 weeks after the submission deadline	Yes	Yes	No	Yes	Yes
Diagnoses circulated by email 2-3 weeks after submission deadline	Yes				
Individual Lab Annual Reports					
Published following moderation of scoring at the Autumn Scientific Advisory Board meeting	Yes	Yes	No	Yes	Yes
Full anonymised scheme results included in AR	Yes				
Scheme Annual Reports (AR)	published in Jan-Feb of the following year				

[9] = see CDG scheme information on page 11

3. 2022 Calendar (provisional)

Please note the schedules in this calendar are provisional only. Please check the EQA calendar on the EQA tab of the ERNDIM website (www.erndim.org), which, from the end of January 2022, will be updated with confirmed dates as they become available.

Year	Month	Quantitative Schemes							Hybrid Schemes				Qualitative Schemes				
		ACS	PPU	QTAS	QTOU	SADB	SAS	SAU	CWBC	LEFB	NCSF	PTU	ACDB	CDG	DPT	QLOU	UMPS
-1	Sep	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
	Oct	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
	Nov	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
	Dec																
Scheme Year	Jan																
	Feb	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D
	Mar																
	Apr	S	S	S	S	S	S	S	S		S	S	S		S		
		S	S	S	S	S	S	S	S		S	S					
	May	S	S	S	S	S	S	S	S	S	S	S		S		S	S
	Jun	S	S	S	S	S	S	S	S		S	S	S		S		
	Jul	S	S	S	S	S	S	S	S		S	S					
	Aug	S	S	S	S	S	S	S	S	S	S	S					
	Sep	S	S	S	S	S	S	S	S		S	S		S		S	S
	Oct	S	S	S	S	S	S	S	S		S	S					
	Nov																
	Dec																
+1	Jan	PSL	PSL	PSL	PSL	PSL	PSL	PSL	PSL	PSL	PSL	PSL	PSL	PSL	PSL	PSL	PSL
	Feb	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
	Mar	AR	AR	AR	AR	AR	AR	AR	AR	AR	AR	AR	AR	AR	AR	AR	AR
		C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C

R = Registration open
D = Sample Dispatch
S = Submission Deadline
PSL = Performance Support Letters sent
A = Appeals open
AR = EQA scheme Annual Reports published
C = Certificates of Participation published

4. 2022 Price List

EQA Schemes	Scheme Code	2022 Prices Euro	GB Pounds	US$
1. Quantitative Schemes				
Acylcarnitines in serum	ACS	364	328	429
Purines and Pyrimidines (urine)	PPU	404	365	476
Quantitative Amino Acids (serum)	QTAS	322	291	380
Quantitative Organic Acids (urine)	QTOU	383	346	452
Special Assays in dried blood spots	SADB	266	240	314
Special Assays (serum)	SAS	209	189	247
Special Assays (urine)	SAU	198	179	233
Special Assays Combined (serum & urine)	SAC	364	328	429
2. Hybrid Schemes				
Cystine in White Blood Cells	CWBC	399	360	470
Lysosomal Enzymes (fibroblasts)	LEFB	687	620	810
Neurotransmitters (CSF)	NCSF	401	362	473
Pterins in Urine	PTU	388	351	458
3. Qualitative Schemes				
Acylcarnitines (dried blood spots) *	ACDB	364	328	429
Congenital Disorders of Glycosylation (serum) *	CDG	372	336	439
Diagnostic Proficiency Testing (urine) *	DPT	519	468	612
Qualitative Organic Acids (urine) *	QLOU	391	353	461
Urine Mucopolysaccharides *	UMPS	349	315	411
Mailing fee per scheme for all laboratories:		**25**	**22**	**29**

Please note:

- VAT at 20% will be added to invoices for all UK laboratories.
- The mailing fee per scheme will added to the invoices for ALL laboratories unless the laboratory provides their own courier account number to be used for sample dispatch.
- * For these schemes a 20% discount on the scheme price is available to participants that donated a sample that was used as an EQA material in the previous scheme year. The Admin Office will automatically add this discount to the invoices for qualifying laboratories after the order has been submitted. For more details please contact admin@erndim.org.

5. Participation Guide

5.1. Registering for EQA Schemes

Registration for the next year's EQA schemes opens in the September of the previous year and is only available for a defined period. For the 2022 EQA schemes, registration will be open from **late September to early November 2021**. In some circumstances late registration may be possible but will be dependent upon sample availability and the

agreement of the relevant Scientific Advisor.

Details of how to access the ERNDIM Registration Website are sent to all existing EQA participants in September of each year and are available from the ERNDIM Administration office upon request.

All EQA scheme orders **must** be submitted using the ERNDIM Registration Website.

If your laboratory already participates in an ERNDIM EQA scheme the Registration Website will show all the contact and address information which is held by ERNDIM for your laboratory.

It is the responsibility of the person listed as the primary laboratory contact to provide the ERNDIM Administration office with valid, up to date contact and address details:

1. The primary laboratory contact should check that all the information is correct and update it where necessary. The information should include:

- Email addresses for a primary and secondary contact persons*
- Email address for named Head of Laboratory or Quality Manager*. *If a laboratory does not supply the contact details for the Head of laboratory or Quality Manager, ERNDIM reserves the right to withhold the laboratory's Certificate of Participation until such time as the contact details are supplied (see section 5.14.).*

** these contact details must be for 3 different people*

- A postal address for the participating laboratory.
- A delivery address for EQA materials.
- An invoice address and named invoice contact with email address.

2. Select the EQA schemes that you wish to participate in during the next year.

3. Add a purchase order number to the registration form, if your hospital or laboratory procedures require it to be on the invoice, and then

4. **Submit** your order.

Any subsequent change in contact persons or address details **must** be sent to the ERNDIM Administration office (admin@erndim.org) as soon as possible.

New participants should email the ERNDIM Administration office to request access to the ERNDIM Registration Website.

If you have any problems with registering for the EQA schemes please contact admin@erndim.org.

5.2. Terms & Conditions of EQA scheme registration

All participant laboratories must accept the terms and conditions on the ERNDIM Registration Website before an EQA scheme order can be submitted. The terms and conditions are on page 22 of this catalogue and can also be viewed on the ERNDIM Registration Website.

5.3. Confidentiality

Laboratory information is confidential and is only shared with the ERNDIM Administration office, the Scientific Advisors and the scheme organisers. All participating laboratories are given a unique ERNDIM reference number which should be used in all correspondence with ERNDIM.

The fact that your laboratory participates in ERNDIM schemes is not confidential, however, the raw data and performance scores are confidential and will only be shared within ERNDIM for the purpose of evaluating your laboratories performance (which may include sharing information between the ERNDIM schemes that you subscribe to), unless ERNDIM is required to disclose performance data by a relevant government agency.

Please see the terms and conditions on page 22 for details of our confidentiality policy for laboratory information; and the ERNDIM Privacy Policy on www.erndim.org, for details of the personal information we collect and store, and your rights regarding that data.

5.4. Use of ERNDIM EQA data in publications

Data derived from the use or analysis of ERNDIM EQA materials **must not** be used in written publications or oral presentations unless the explicit prior consent of ERNDIM has been granted.

If you wish to use data derived from ERNDIM EQA materials you **must** contact the Administration Office to obtain permission **before** publication.

For EQA materials based on real clinical samples, permission to use the data will be dependent on the appropriate consent being in place.

If permission to use the data is granted, ERNDIM must be acknowledged in the publication or presentation using a standard acknowledgement sentence which will be provided by the ERNDIM Administration Office, and a copy of the publication, with full reference/citation information, should be sent to the ERNDIM Administration Office.

5.5. EQA participation fees

The price list for the 2022 EQA schemes can be found on page 15 of this catalogue.

A mailing charge per scheme will be added to the EQA order unless the you provide the details of a courier account to be used for the sample dispatch.

VAT at 20% will be added to invoices for all UK laboratories.

5.6. Laboratory Support Grants

A limited number of Laboratory Support Grants are available to provide financial support for laboratories which due to financial restrictions find it difficult to fund participation in one or more of the ERNDIM EQA schemes.

Laboratory Support Grants are awarded annually by the ERNDIM Board on a competitive basis with the aim of allowing laboratories to extend their repertoire of EQA scheme participation.

If you would like to apply for a Laboratory Support Grant please complete and return the application form, which can be found on the ERNDIM website under Training/Grants.

Applications for support during the 2022 scheme year must be received by the Administration Office during the registration period.

5.7. Educational participation

Educational Participation is open to laboratories that are participating in an EQA scheme to help with setting up a new test but are not yet offering a clinical service.

Participants that select Educational Participation when registering for an EQA scheme MUST send a completed and signed Educational Declaration form to the ERNDIM Administration office.

Educational Participation in a scheme is not confirmed until the Administration office confirms that your application has been accepted.

Please note the number of Educational Participants per scheme is limited and Educational Participation is not available for the DPT scheme.

The Educational Participation Declaration forms can be found on the ERNDIM Registration website (www.erndim.org/qa) under Participant Information. There is one form for the qualitative schemes and separate forms for each of the quantitative and hybrid schemes.

For each EQA scheme in which you wish to be an Educational Participant, a separate Declaration form needs to be completed, and sent to admin@erndim.org,

5.8. Sample Donation

Several of the ERNDIM EQA schemes use real clinical samples as the EQA materials however, it is becoming increasingly difficult to source suitable clinical samples. Details of the types of samples that would be useful to ERNDIM can be found on the EQA tab of the ERNDIM website. If you think you would be able to donate a clinical sample (with the appropriate patient consent) to ERNDIM please contact admin@erndim.org.

5.8.1. Scheme Discounts

If a sample donated by your laboratory is used as an EQA material in one of the Qualitative EQA schemes, you will qualify for a 20% discount on the cost of that specific scheme when you register for the following scheme year. The Administration office automatically applies this discount to orders from qualifying laboratories once the order has been submitted.

The maximum discount that can usually be applied is 20% per laboratory per scheme regardless of how many donated samples are used in a scheme year.

5.9. EQA scheme timetables

A provisional EQA calendar is on page 14. From the end of January in each year, the EQA calendar will also be available to download on the ERNDIM website under EQA schemes. Information is added to the calendar as it becomes available.

5.10. Sample Dispatches

Sample dispatch dates will be given on the

ERNDIM website by the end of January. Additionally, all participants will be sent emails with dispatch information 3-6 weeks before sample dispatch.

5.10.1. Replacement Samples

If you do not receive the EQA sample parcel within the time specified in the sample dispatch alert email please contact the ERNDIM Administration Office (admin@erndim.org).

5.11. Analysis and Reporting

You will receive instructions on sample testing and reporting processes with the sample shipments. Scheme instructions will also be available to download from the ERNDIM Registration website (www.erndim.org/qa) under Participant Information, or by contacting admin@erndim.org.

EQA samples must be treated in the same way as clinical samples.

Details of the submission deadlines for each scheme are given in the scheme instructions you will receive with the sample parcel and in the EQA calendar on the EQA schemes tab of the ERNDIM website (www.erndim.org). EQA scheme instructions can also be downloaded from the Registration Website (www.erndim.org/qa) under Participant Information.

Reports and results will be released according to individual scheme timetables. **Please note: Data derived from any EQA reports should not be used in any written publications or oral presentations unless the explicit prior consent of ERNDIM has been granted. See item 5.4 for details.**

If a laboratory persistently does not submit results, or submits insufficient results for performance to be assessed this will be shown on the Certificate of Participation. ERNDIM also reserves the right to restrict the laboratory's participation in the EQA scheme(s) in future years.

5.11.1. Late results submission or amending submitted results

We strongly recommend that all submitted results are printed and checked before the relevant deadline. If you do miss a submission deadline or realise after the deadline that you need to amend an already submitted result please contact admin@erndim.org as soon as possible.

However, please note that extensions will only be allowed under exceptional circumstances and no late/amended results can be accepted if the relevant consensus results or diagnoses have already been published.

5.12. Final Scheme Annual reports

For each EQA scheme an Annual report is published after the end of the scheme year. All the available EQA scheme Annual reports can be downloaded from the ERNDIM website under Meeting and Reports.

Please note: Data derived from EQA scheme annual reports should not be used in any written publications or oral presentations unless the explicit prior consent of ERNDIM has been granted. See item 5.4 for details.

5.13. Performance Assessment

Submitted results are evaluated according to ERNDIM policies and procedures, which are available upon request.

The number of points required for satisfactory performance in each EQA scheme is defined by the Scientific Advisor, ratified by the Scientific Advisory Board (SAB) and is reviewed annually.

Satisfactory performance in an EQA scheme is based solely on the laboratory's performance in that scheme year and does not guarantee future performance.

ERNDIM is not responsible for the performance of participating laboratories.

5.13.1. Critical Errors

For the Qualitative and Hybrid EQA schemes any errors which would be unacceptable to the majority of laboratories will be separately assessed as Critical Errors.

An absence of Critical Errors is required for satisfactory performance. Any laboratory that makes a Critical Error will be classed as a poor performer regardless of their overall score in the EQA scheme.

The critical errors for each scheme year will be proposed by the Scientific Advisors for the individual EQA schemes and will be ratified at the SAB Meeting held after the completion of the EQA scheme year.

Lists of the Critical Errors agreed for previous scheme years can be found on the ERNDIM website under Meetings & Reports\Reports.

5.13.2. Performance Support Letters

Laboratories that have unsatisfactory performance or fail to return sufficient results will be sent a Performance Support Letter by ERNDIM.

The aim of the performance support letter is to begin a dialogue between the Scientific Advisor and the participating laboratory in order to solve any particular analytical problems and to help the laboratory improve performance.

If a laboratory does not respond to the Performance Support Letter ERNDIM reserves the right to contact the Laboratory Head or Quality Manager.

Performance Support Letters will also be sent to the Laboratory Head or Quality Manager for cases of Global poor performance (poor performance in more than one EQA scheme in one year) and Persistent Poor Performance (poor performance in an EQA scheme for at least 2 out of 3 years during which the participant has submitted results).

In the rare instances that a lab is a persistent global poor performer (poor performance in more than one EQA scheme in at least 2 out of 3 participating years) ERNDIM reserves the right to contact the administration of the relevant institution.

5.14. Certificates of Participation

A certificate showing which EQA schemes you have registered for, participated in and your laboratory's performance in those schemes is issued after the end of the scheme year when all scheme results have been finalised.

ERNDIM reserves the right to withhold the certificate of participation in cases where:

- The relevant ERNDIM invoice has not been paid
- The Head of Laboratory or Quality Manager Contact has not been provided
- A laboratory has been found to be colluding, or is strongly suspected of colluding, with another laboratory (see section 5.15).

5.15. Collusion

Participants found to be colluding, or which are strongly suspected of colluding, with another laboratory in their scheme returns may have their certificates of participation withheld and be excluded from participation in future schemes.

5.16. Appeals, Complaints & Feedback

Problems relating to EQA Schemes, including appeals and complaints from participating laboratories, should be referred directly to the ERNDIM Administration Office (admin@erndim.org).

5.16.1. Appeals

If you wish to appeal against the evaluation of your laboratory's performance in an EQA scheme a formal appeal must be submitted in writing to the ERNDIM Administration Office within 4 weeks of the date of the performance support letter.

Appeals against classification as a poor performer due to score are initially considered by the EQA scheme Scientific Advisor with any further appeals being considered by the ERNDIM Executive Committee.

Appeals against classification as a poor performer due to a critical error will be considered by the ERNDIM Executive Committee.

Please note that appeals which will not affect the overall classification of a lab as a satisfactory or poor performer, will not be considered.

5.16.2. Complaints

If a complaint is received it will be logged along with the action taken. The office staff will attempt to address the complaint as soon as possible. If the participant is not satisfied with the response then the matter will be brought to the ERNDIM Executive Committee at their next meeting and a response made in light of their advice.

5.16.3. Feedback to ERNDIM

Confidential communications about a scheme can be made to the ERNDIM Administration Office.

A participant survey is also conducted annually. The results of this survey are shared with the ERNDIM Management Committees and a survey report is uploaded to the ERNDIM website under Meetings and Reports.

5.17. Subcontracted Activities

Some activities such as the manufacture of materials, dispatch of samples and hosting and maintenance of websites are subcontracted but ERNDIM remains responsible for the oversight of subcontracted activities.

Details of the sub-contracted activities for each scheme are included in the scheme information in section 2 of this catalogue and are also available on

the EQA schemes tab of the ERNDIM website (www.erndim.org).

5.18. Training Support Grants

As part of our aim to help improve standards in biochemical genetic testing ERNDIM offers a small number of Training Support Grants each year.

This grant is designed for trainees, in a permanent laboratory position, to gain experience and knowledge in a European ERNDIM approved laboratory in order to develop or introduce new methods to their own laboratory.

Funds can be applied for to cover the travel and accommodation costs incurred by such visits and a maximum of 6 grants will be awarded each year, subject to the approval of the ERNDIM Executive Committee. Full application criteria are given in the application form which can be found on the ERNDIM website under Training/Grants.

5.19. Invoicing & Payment Information

5.19.1. Invoices

For participants that submit an EQA scheme order by the Registration deadline, invoices will be sent out in November/December and will be dated 1st January of the following year, as requested by a number of laboratories.

If your hospital or laboratory procedures require a purchase order number be included on the invoice, this should be added to your order on the ERNDIM Registration Website.

If you receive a purchase order number from your finance department after the Registration period has closed, please send it to the Administration Office as soon as possible so it can be added to your invoice.

The invoice payment date will be stated on the invoice but for orders submitted within the Registration period, **invoice payments must be received by ERNDIM by 1st April in the scheme year**, unless an earlier date (due to late payment of a previous invoice) or later date (due to late registration) is specified.

The invoice of participants that submit a late registration request will be dated with the issued date and the payment date will be 1st April or 8 weeks from the issued date, whichever is later.

Invoices show:

- The EQA schemes chosen.
- The subscription fees for those schemes and associated mailing charges.
- Any discounts applied due to sample donation or awarded grants.
- Any balance brought forward from previous invoices.

Invoices will be sent **by email only** to the primary, secondary and invoice contacts for each laboratory. It is the responsibility of the primary laboratory contact to ensure they provide a valid invoice address, invoice contact name and invoice email address.

The participant **must** check the information in the invoice. If all details are correct the invoice should be passed for payment to the appropriate finance department.

If any details on the invoice are not correct the ERNDIM Administration office (admin@erndim.org) should be notified by mid-December and a revised invoice will be issued.

It is the responsibility of the participant laboratory to ensure that the ERNDIM invoice is paid.

Late payment will incur penalties as specified below:

- Interest charges of 1.3% per month are applied to outstanding balances after the invoice payment date. When interest is added to the outstanding balance an updated invoice with a new version number will be sent to the participant.
- If there is still an outstanding invoice balance after the 1st July, in the next year the invoice payment date will be 31st January and the dispatch of samples to the laboratory in that year will be delayed until ALL outstanding invoices have been paid.
- If there is still an outstanding invoice balance after the 1st August, access to the EQA scheme results will be restricted until the invoice has been paid.
- If there is still an outstanding invoice balance after the 1st September, in the same year as the scheme participation, the laboratory will not be eligible to register for any ERNDIM EQA schemes until all outstanding invoices have been paid and a Certificate of Participation for the current year will not be issued.

5.19.2. Payment Information

ERNDIM accepts payments in Euro, GB pounds or US dollars and it is important that the correct bank account is used for payments in each currency.

Payments which are made into the wrong bank account (for example a payment in Euros paid into the GB pounds account) can result in losses due to the bank exchange rate. **Any losses which are a result of a participant making a payment into the wrong ERNDIM bank account, will be borne by the participant.**

ERNDIM is responsible solely for paying its own bank charges. Any other charges related to invoice payments must be paid by the participant.

All correspondence and invoice payments should contain your laboratory's ERNDIM reference number (ERNxxxx) otherwise it may not be possible to match the payment to the correct account.

ERNDIM bank accounts.

- For payments in **Euros and US Dollars** please use the ING account:

  ERNDIM Bank Account
  ING, B4300 Waremme, Belgium
  Account Number: 340-0876266-06
  SWIFT Address: BBRU BE BB
  IBAN: BE85340087626606

- For payments in **GB Pounds** please use the Barclays account:

  ERNDIM Bank Account
  Barclays Business Centre, 2 Arena Court,
  Sheffield, S9 2LF, UK
  Account Number: 70540900
  Sort Code: 20 76 89
  SWIFT Address: BARCGB22
  IBAN: GB50BARC20768970540900

- If paying by **cheque or Bank Draft,** it should be made payable to 'ERNDIM' and sent to:

  ERNDIM Accountant
  The Accounting House,
  Sheepbridge Lane,
  Chesterfield, S41 9RX
  United Kingdom

6. Terms and Conditions of EQA Scheme Participation for Participating Centres

Use of data derived from ERNDIM EQA Materials

1. Data derived from the use or analysis of ERNDIM EQA materials **must not be** used in written publications or oral presentations unless the explicit prior consent of ERNDIM has been granted.

    1. If a participating laboratory wishes to use such data in a publication or presentation, they **must** contact the ERNDIM Administration Office before submitting any documents for publication.
    2. For EQA materials based on real clinical samples, permission to use the data will be dependent on the appropriate consent being in place.
    3. If permission to use the data is granted: a) ERNDIM must be acknowledged in the publication or presentation using a standard acknowledgement sentence which will be provided by the ERNDIM Administration Office, and b) after the data has been published a copy of the publication, with full reference/citation information, should be sent to the ERNDIM Administration Office.

Registering for EQA Schemes

2. When registering for ERNDIM EQA schemes it is the responsibility of the person listed as the laboratory primary contact to provide the ERNDIM Administration office with valid, up to date contact and address details, which should include:

    1. Email and postal addresses for a primary and secondary contact persons* (these contacts will be used for all routine ERNDIM correspondence)
    2. Email address for named Head of Laboratory or Quality Manager* (this contact will only be used in certain cases of poor performance)
    3. A postal address for the registering Laboratory
    4. A delivery address for EQA materials
    5. An invoice address and named invoice contact with email address

    ** these contact details must be for **3 different people***

Any subsequent change in contact persons or address details **must** be sent to the ERNDIM Administration Office as soon as possible.

3. Participants are responsible for ensuring that they have obtained any import or other permits required for delivery of the EQA materials and for sending these to the ERNDIM Administration office during the Registration period.

4. Mailing charges (per scheme) will be added to the EQA order unless the participant provides the details of a courier account to be used for the sample dispatch. Any additional customs charges will be paid by the participant.

5. For participants that submit an EQA scheme order by the Registration deadline, invoices will be sent out in November/December and will be dated 1st January of the following year, as requested by a number of laboratories.

Invoices and Payments

6. If your hospital or laboratory procedures require a Purchase Order number on the invoice, this should be added to the registration form.

7. Invoices will be sent **by email only** to the primary, secondary and invoice contacts for each laboratory. It is the responsibility of the primary laboratory contact to provide a valid invoice address, invoice contact name and invoice email address.

8. The participant **must** check the information in the invoice. If all details are correct the invoice should be passed for payment to the appropriate finance department. If any details on the invoice are not correct the ERNDIM Administration office (admin@erndim.org) should be notified by mid-December and a revised invoice will be issued.

9. The invoice payment date will be stated on the invoice but for orders submitted within the registration period, **invoice payments must be received by ERNDIM by 1st April in the scheme year**, unless an earlier date (due to late payment of a previous invoice) or later date (due to late registration) is specified.

10. For participants that submit a late registration request any invoices will be dated with the issued date and the payment date will be 1st April or 8 weeks from the issued date, whichever is later.

11. It is the responsibility of the participant laboratory to ensure that the ERNDIM invoice is paid.

12. ERNDIM accepts payments in Euro, GB pounds or US dollars and it is important that the correct bank account is used for payments in each currency. Payments which are made into the wrong bank account (for example a payment in Euros paid into the GB pounds account) can result in losses due to the bank exchange rate. Any losses which are a result of a participant making a payment into the wrong ERNDIM bank account will be borne by the participant.

13. ERNDIM is responsible solely for paying its own bank charges. Any other charges related to invoice payments must be paid by the participant.

14. Penalties for late payment of invoices are:

    1. Interest charges of 1.3% per month are applied to outstanding balances after the invoice payment date. When interest is added to the outstanding balance an updated invoice with a new version number will be generated;
    2. If there is still an outstanding invoice balance after the 1st July, in the following year the invoice payment date of any invoices will be 31st January and the dispatch of samples to the laboratory in the that year will be delayed until ALL outstanding invoices have been paid;
    3. If there is still an outstanding invoice balance after the 1st August, access to the EQA scheme results will be restricted until the invoice has been paid;
    4. If there is still an outstanding invoice balance after the 1st September, in the same year as the scheme participation, the laboratory will not be eligible to register for any ERNDIM EQA schemes until all outstanding invoices have been paid and a Certificate of Participation for the current scheme year will not be issued.

EQA Scheme Participation

15. EQA samples must be treated in the same way as clinical samples.

16. Compliance with the EQA submission deadlines is a requirement of satisfactory participation in the EQA schemes.

1. Requests for late submissions will only be allowed under exceptional circumstances and as such requests for late submission should not be needed on multiple occasions.
2. No late/amended results can be accepted if the relevant consensus results or diagnoses have already been published.

17. Participants must not collude with other laboratories on the results of their EQA scheme participation. This includes the use of cluster labs unless these are specifically allowed in the individual EQA scheme (e.g. DPT scheme).

1. Laboratories which have been found to have colluded and/or falsified results will be excluded from participating in future EQA schemes and where necessary, the relevant competent authority will be notified.
2. In cases where collusion is strongly suspected, ERNDIM reserves the right to withhold the certificate of participation for the specified scheme year from the relevant laboratories.

18. All participating laboratories are given a unique ERNDIM reference number which should be used on all invoice payments and in all correspondence with ERNDIM.

19. The fact that your laboratory participates in ERNDIM schemes is not confidential, however, the raw data and performance scores are confidential and will only be shared within ERNDIM for the purpose of evaluating your laboratory's performance, (which may include sharing information between the ERNDIM schemes that you subscribe to) except in these circumstances:

1. Performance information of United Kingdom laboratories is shared with NQAAP.
2. If ERNDIM is approached by other equivalent national bodies, ERNDIM may share performance information with those bodies, but in that case the labs concerned would be informed in advance. For countries with fewer than 5 participating laboratories, to preserve anonymity, only regional data will be shared.

Performance Evaluation

20. Satisfactory performance in an EQA scheme is based solely on the laboratory's performance when analysing the QA samples supplied in that scheme year. By participating in ERNDIM schemes participants agree to these terms and conditions. Performance assessment of scheme participation is described in the ERNDIM quality documents (available on request).

21. ERNDIM is not responsible for the performance of participating laboratories when offering a clinical diagnostics service.

22. Laboratories that have unsatisfactory performance will be sent a Performance Support Letter by ERNDIM. If a laboratory does not respond to the Performance Support Letter, or has persistent unsatisfactory performance, ERNDIM reserves the right to contact the Laboratory Head or Quality Manager.

23. For laboratories that have unsatisfactory performance in more than one EQA scheme during one scheme year (i.e. Global Poor Performance) ERNDIM reserves the right to contact the Laboratory Head or Quality Manager. For laboratories that have persistent Global Poor Performance ERNDIM reserves the right to contact the CEO or equivalent of the relevant institution.

24. Laboratories that do not submit any results, or do not submit sufficient results for their performance to be evaluated, will be sent a Non-submission letter. If a laboratory does not respond to the Non-submission Letter, or persistently does not submit sufficient results for their performance to be evaluated ERNDIM reserves the right to contact the Laboratory Head or Quality Manager and may restrict eligibility for future scheme years.

25. If a laboratory does not supply the contact details for the Laboratory Head or Quality Manager, ERNDIM reserves the right to withhold the laboratory's Certificate of Participation until such time as the contact details are supplied.

Data Protection & Privacy

26. Any personal information you supply to ERNDIM via this website will be treated in accordance with the ERNDIM Privacy Policy (which can be found on www.erndim.org) and the UK's Data Protection Act 2018, which is the UK's implementation of the EU General Data Protection Regulation (GDPR) 2016.

27. By using this website, you consent to ERNDIM processing any data you provide in line with the ERNDIM Privacy Policy and confirm that all data provided by you is accurate. If there are any changes to the data you have provided, it is your responsibility to update such data.

Problems & Complaints

28. Problems relating to EQA Schemes, including complaints from participating laboratories should be referred directly to the ERNDIM Administration Office (admin@erndim.org).

Copyright

29. All documents, and the data they contain, issued by ERNDIM are copyright and must **not** be published in any form without the permission of the ERNDIM Executive Committee.