ERNDiM

Quality Assurance in Laboratory Testing for IEM

EQA Schemes Catalogue and Participant Guide 2025

ERNDIM Administration Office
c/o EMQN CIC, Unit 4, Enterprise House,
Manchester Science Park,
Pencroft Way, Manchester,
M15 6SE, United Kingdom
Tel: +44 161 757 4952
Fax: +44 161 850 1145
E-mail: admin@erndim.org
Web: www.erndim.org

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Version Date	Amendments
16th September 2024	• 2025 EQA Catalogue published
10th December 2024	• Page 7: Updated quantitative EQA schemes' summary table with addition of gentamicin to SAS samples
19th February 2025	• Page 4: PPU information – Orotidine removed from list of analytes included in the scheme

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 410 participants from over 60 countries, with approximately 40% of our participants coming from outside of Europe in 2024.

In 2025 we will be operating 17 EQA schemes which are developed & monitored by a Scientific Advisory Board comprising 22 leading scientists from 10 countries. You can find full details of the EQA schemes in section 2 (pages 4 to 14) and details of how to register to participate in the 2025 schemes in section 5 (pages 17 to 22).

The Participants' Guide on pages 17 to 22 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 23 to 24. 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 2025 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 (type and number of samples, 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 <u>not</u> 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 (2025):

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 EQA scheme since 2000

Analytes (2025):

5-OH Methyluracil	Deoxy-guanosine	Pseudo-uridine
3-Ureidoisobutyric acid	Deoxy-inosine	Succinyl adenosine
3-Ureidopropionic acid	Deoxy-uridine	Thymidine
Adenine	Dihydro-thymine	Thymine
Adenosine	Dihydro-uracil	Uracil
AICAriboside	Guanosine	Uric acid‡
Creatinine (mmol/L)‡	Hypoxanthine	Uridine
Cytidine	Inosine	Xanthine
Deoxy-adenosine	Orotic acid	

‡ Analytes marked with ‡ are present in the matrix so results can be recorded for comparison between labs <u>BUT</u> the concentrations do not vary, and they are not included in the Individual Online Annual Reports or Certificates of participation

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

Scheme Organiser: MCA†

† Full details of the scheme design 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 EQA scheme since 1993

Analytes[1] (2025):

2-Aminobutyric acid	Cystine	Lysine	Taurine
Alanine	Glutamic acid	Methionine	Threonine
Allo-isoleucine	Glutamine	Ornithine	Tryptophan
Arginine	Glycine	Phenylalanine	Tyrosine
Argininosuccinic acid	Histidine	Proline	Valine
Asparagine	Hydroxyproline	Sarcosine	
Aspartic acid	Isoleucine	Serine	
Citrulline	Leucine	Sulfocysteine	

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 EQA scheme since 1993

Analytes (2025):

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

‡ Analytes marked with ‡ 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: 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: Full EQA scheme since 2019

Analytes (2025):

Allo isoleucine	Methionine	Tyrosine
Isoleucine	NTBC (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 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 EQA scheme since 1993

Analytes (2025):

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

‡ Analytes marked with ‡ 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 EQA scheme since 1993

Analytes (2025):

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 (HVA)	Succinylacetone
Creatinine	Lactic acid	Sulfocysteine
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 16).

† Full details of the scheme design 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. For the provisional 2025 scheme calendar, see Section 3 on page 15.

Detailed scheme information on page:	ACS	PPU	QTAS	QTOU	SADB	SAS	SAU
	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						
Educational participation allowed? *	Yes						
No. of registrations (2024):	129	52	276	136	121	277	212
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
Sample treated with gentamicin	No					Yes	No
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						
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						
Scheme Annual Reports (AR)	published in Jan-Mar of the following year						
Full anonymised scheme results included in AR	No						

***** = For more information on Educational Participation see page 17 in the Participants' Guide section of this catalogue.

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 (type and number of samples, 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 EQA scheme since 2005

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

Volume/sample: Lyophilised pellet and 250µl supernatant equivalent to extracts from 5 ml whole blood samples

Sample matrix: Lyophilised pellet from protein standard, WBC supernatants are liquid

Analytes (2025): Cystine (nmol/aliquot) (250 µL SNT sample)
Protein (mg/pellet) (PP sample)
Cystine (nmol 1/2 cys/mg protein, calculated as if isolated from 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 EQA scheme since 2011

Expected Enzymes (2025):

- Acetyl-CoA-glucosamine acetyltransferase
- Alpha-galactosidase
- Alpha-glucosidase
- Arylsulphatase A
- Arylsulphatase B
- Beta-galactosidase
- Beta-glucosidase
- Beta-mannosidase
- Iduronate sulphatase
- Tripeptidyl peptidase 1
- Protein

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

Scientific Advisor: Dr Ed Jacobs, 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: Full EQA scheme since 2016

Analytes (2025):

- 3-methyl dopa (3-MD)
- 5-OH-Indolacetic acid (5-HIAA)
- 5-OH-Tryptophan (5-HTTP)
- 5-methyltetrahydrofolate (5-MTHF)
- Biopterin
- Homovanillic acid (HVA)
- HVA:5-HIAA ratio
- Neopterin

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

Scheme Organiser: MCA[††]

[††] Full details of the scheme design 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: Full EQA scheme since 2017

Analytes (2025):
- 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 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. For the provisional 2025 scheme calendar, see Section 3 on page 15.

Detailed scheme information on page:	CWBC		LEFB	NCSF	PTU
	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				
Educational participation allowed? *	Yes				
No. of registrations (2024):	42		71	38	36
Geographic area:	Worldwide				
EQA Samples					
Sample volume/vial	Lyophilised protein pellet	250µl supernatant	0.5 mg lyophilised protein	1ml	1ml
Sample type					
Artificial/human matrix spiked with commercially available analytes				Yes	
Clinical samples			Yes		
Matrix of human origin, with commercially available analytes		Yes			Yes
Matrix:					
Lyophilised cerebrospinal fluid				Yes	
Lyophilised fibroblasts			Yes		
Lyophilised protein	Commercial protein standard (human origin)				
Lyophilised urine					Yes
White blood cells		Yes			
Scheme Design					
Sample design/selection:	Scientific Advisor for each scheme				
Sample manufacture subcontracted to:	MCA		CHU Lyon & MCA	MCA	University Children's Hospital, Zurich & 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[3]		6	8	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				
Interpretation results submission is mandatory	Yes				
Scoring of results:					
Analysis scored	Yes				
Diagnoses Scored	Yes				
Reports:					
Interim Reports					
Published after each submission deadline (no. days)	21				
Individual Lab Annual Reports					
Published after the submission deadline	Jan		-	Jan	Jan
Scheme Annual Reports (AR)	published in Jan-Mar of the following year				
Full anonymised scheme results included in AR	-		Yes	-	-

[3] = 8 pairs of protein and WBC supernatants, see page 8.

***** = For more information on Educational Participation see page 17 in the Participants' Guide section of this catalogue.

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 14.

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

Sample Donations

For some 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: Heidelberg: Dr Joachim Janda, admin@erndim.org
London: Mrs Erin Emmett, admin@erndim.org
Rome: Dr Cristiano Rizzo, admin@erndim.org

Scheme Organisers: CSCQ†††

Amino Acids Interpretation††† — Scheme Code: AAI

Aim: To educate and assess the ability of laboratories to detect inherited disorders resulting in recognisable patterns of amino acids in plasma and other specimens

Status: Running as a full EQA scheme for the first time in 2023 (previously ran as a pilot scheme in 2017-2019 & 2021-2022)

Eligibility Requirements: Participating laboratories must carry out the interpretation of the EQA sample data. **The use of cluster laboratories is not allowed.**
The number of participants for 2025 is limited, with previous participants taking priority.

Samples: Clinical information and quantitative values for amino acids in plasma, urine and CSF (with reference ranges) are circulated.
Note: samples are data only, no physical samples are circulated for this scheme

Analytes: Amino acids in plasma (data only)

Scientific Advisor: Dr Sabine Scholl-Bürgi, admin@erndim.org

Scheme Organisers: ERNDIM, admin@erndim.org

††† Full details of the scheme design for each of the Qualitative schemes are given in section 2.3.1 on page 14.

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 EQA scheme since 2010

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†††

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
Heidelberg: Dr Joachim Janda, admin@erndim.org
Sheffield: Mrs Camilla Scott, admin@erndim.org

Scheme Organiser: CSCQ†††

††† Full details of the scheme design for each of the Qualitative schemes are given in section 2.3.1 on page 14.

Urine Mucopolysaccharides††† — Scheme Code: UMPS

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

Status: Full EQA scheme since 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 for each of the Qualitative schemes are given in section 2.3.1 on page 14.

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 13. For the provisional 2025 scheme calendar, see Section 3 on page 15.

	DPT	AAI	ACDB	CDG	QLOU	UMPS
Detailed scheme information on page:	p12	p11	p11	p12	p12	p13
General						
Method Orientated scheme?	No	Yes				
Eligibility Requirements:	See DPT information on p12	Participants must produce their own results and cannot send samples/cases to a sub-contracted (or cluster) laboratory				
Use of cluster labs allowed?	Yes	No				
Educational participation allowed? *	No		Yes			
No of organising centres:	5	1	3	1	3	1
No. of registrations (2024):	96 (17-21 per centre)	143	134 (44-45 per centre)	95	235 (77-80 per centre)	95
Geographic area:	Worldwide					
EQA Samples						
Sample volume/vial:	5-10ml	n/a	30-50µl	25 µl[4]	2-3 ml/vial	5ml
Sample type	Clinical samples	Data from clinical samples	Clinical samples			
Matrix:						
Data from plasma, urine & CSF samples		Yes				
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	n/a	SA	MCA	CSCQ	MCA
Sample Dispatch subcontracted to: (one dispatch per year)	CSCQ	n/a	CSCQ	MCA	CSCQ	MCA
Country samples will be dispatched from:	Switzerland	n/a	Switzerland	Netherlands	Switzerland	Netherlands
No of samples/year	6					
Results Submissions						
No of submission deadlines/year	2					
Submission of results	Online (ERNDIM-CSCQ website)	Online (ERNDIM form)	Online (ERNDIM-CSCQ website)			
Scoring of results:						
Analysis of physical samples	Yes	No	Yes			
Analysis of data samples only	No	Yes	No			
Interpretation, including diagnoses	Yes					
Reports:						
Interim Reports						
Published 8-10 weeks after the submission deadline	Yes	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					
Scheme Annual Reports (AR)	Published in Jan-Mar of the following year					
Full anonymised scheme results included in AR	Yes					

[4] = see CDG scheme information on page 12

* = For more information on Educational Participation see page 17 in the Participants' Guide section of this catalogue.

3. 2025 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 2025, 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	AAI	CDG	DPT	QLOU	UMPS
-1	Sep	R	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	R
	Nov	R	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	S	S	S	S	S	S	S	S		S	S						
	Apr	S	S	S	S	S	S	S	S		S	S	S			S		
	May	S	S	S	S	S	S	S	S	S	S	S		D 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		D				
	Sep	S	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	PSL
	Feb	A	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	AR
		C	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. 2025 Price List

EQA Schemes	Scheme Code	2025 Prices Euro	GB Pounds	US$
1. Quantitative Schemes				
Acylcarnitines in serum	ACS	413	373	487
Purines and Pyrimidines (urine)	PPU	459	414	541
Quantitative Amino Acids (serum)	QTAS	365	330	431
Quantitative Organic Acids (urine)	QTOU	435	393	513
Special Assays in dried blood spots	SADB	302	272	357
Special Assays (serum)	SAS	237	214	280
Special Assays (urine)	SAU	225	203	265
Special Assays Combined (serum & urine)	SAC	413	373	487
2. Hybrid Schemes				
Cystine in White Blood Cells	CWBC	453	409	534
Lysosomal Enzymes (fibroblasts)	LEFB	780	704	920
Neurotransmitters (CSF)	NCSF	455	411	537
Pterins in Urine	PTU	441	398	520
3. Qualitative Schemes				
Acylcarnitines (dried blood spots) *	ACDB	413	373	487
Amino Acids Interpretation	AAI	165	140	169
Congenital Disorders of Glycosylation (serum) *	CDG	423	381	498
Diagnostic Proficiency Testing (urine) *	DPT	589	532	695
Qualitative Organic Acids (urine) *	QLOU	444	401	524
Urine Mucopolysaccharides *	UMPS	396	357	467
Mailing fee per scheme for all laboratories:		**31.50**	**27**	**37**

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 2025 EQA schemes, registration will be open from **mid September to early November 2024** (see www.erndim.org for the exact dates). 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 (www.eqa.erndim.org) 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 23 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 laboratory's 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 23 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 2025 EQA schemes can be found on page 16 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 EQA Schemes/Laboratory Support Grants.

Applications for support during the 2025 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 AAI or DPT scheme.

The Educational Participation Declaration forms can be found on the ERNDIM Registration website (www.eqa.erndim.org) 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 schemes 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 15. 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, but are usually in early February. Additionally, all participants will be sent emails with dispatch information 1-2 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.eqa.erndim.org) 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.eqa.erndim.org) 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\Other 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 using the online appeals form (link included in the performance support letter), 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 Executive Committee.

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 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 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.eqa.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/Training Support 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 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 MUST 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** please use:

  STICHING ERNDIM QAP
  Barclays Bank PLC, SHEFFIELD CITY,
  Leicester, LE87 2BB, UK
  Account Number: 65615322
  Sort Code: 20-76-89
  SWIFT Address: BUKBGB22
  IBAN: GB76 BUKB20768965615322

- For payments in **GB Pounds** please use:

  STICHING ERNDIM QAP
  Barclays Bank PLC, SHEFFIELD CITY,
  Leicester, LE87 2BB, UK
  Account Number: 70540900
  Sort Code: 20-76-89
  SWIFT Address: BUKBGB22
  IBAN: GB59 BUKB20768970540900

- For payments in **US Dollars** please use:

  STICHING ERNDIM QAP
  Barclays Bank PLC, SHEFFIELD CITY,
  Leicester, LE87 2BB, UK
  Account Number: 44300511
  Sort Code: 20-76-89
  SWIFT Address: BUKBGB22
  IBAN: GB40 BUKB20768944300511

- ERNDIM only accepts payments **by cheque or bank draft in GB Pounds.** If paying by cheque or bank draft in GBP, it should be made payable to 'ERNDIM' and sent to:

  ERNDIM Administration Office,
  c/o EMQN CIC, Unit 4, Enterprise House,
  Manchester Science Park,
  Pencroft Way, Manchester,
  M15 6SE, 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 or if the primary and secondary persistently do not respond to ERNDIM correspondence)
    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 on more than one occasion will not routinely be accepted.
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 and may also exclude the laboratories from participating in future EQA schemes.

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).

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