

Quality Assurance in Laboratory Testing for IEM

EQA Schemes Catalogue and Participant Guide 2026

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Version Date	Amendments
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1. Introduction

ERNDIM is an independent, not-for-profit foundation that has been delivering External Quality Assurance (EQA) schemes in the field of inborn errors of metabolism since 1994. Originally established as a European initiative, ERNDIM has grown into a global organisation, now supporting over 410 participants across more than 60 countries. As of 2025, approximately 42% of our participants are based outside Europe.

In 2026, ERNDIM will offer 18 EQA schemes, including the launch of a new scheme developed in response to participant feedback: **Lipids in Serum (LIS)**. This quantitative scheme builds on two years of pilot testing and features a panel of lipids, some of which have been moved from the SAS scheme (see page 6 for details), and others newly introduced. Our aim is to expand the LIS panel over time to include additional diagnostically valuable markers.

All ERNDIM schemes are designed and overseen by our Scientific Advisory Board, which comprises 23 leading scientists from 10 countries. Full details of the 2026 EQA schemes are available in **Section 2 (pages 4–14)**, and guidance on how to register is provided in **Section 5 (pages 17–22)**. Some activities are subcontracted to scheme organisers however ERNDIM remains responsible for all work. For further details see the Summary tables for each type of scheme (pages 7, 10 and 14) and Section 5.17 (page 20).

The **Participants' Guide** (pages 17–22) contains essential information on scheme participation, including registration procedures, use of EQA data in publications, and payment instructions. For any queries related to the guide, please contact us at admin@erndim.org.

Please also review the **Terms and Conditions of Participation** (pages 23–24). These must be accepted by your centre's primary contact upon first login to the ERNDIM Registration Website, once registration for the 2026 schemes opens. 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. The schemes assess accuracy with respect to consensus target values, as well as recovery of spiked analytes, analytical precision and linearity.

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 Laboratories

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; several acylcarnitines were previously included in the Special Assays in Serum scheme.

Analytes (2026): 3-OH- Butyrylcarnitine (C4-OH)

3-OH- Butyrylcarnitine (C4-OH)
3-OH-Isovalerylcarnitine (C5-OH)
3-OH- Palmitoylcarnitine (C16-OH)
3-OH-Stearoylcarnitine (C18-OH)
Methylmalonylcarnitine (C4-DC)

Acetylcarnitine (C2)

Butyrylcarnitine (C4)

Cis-5-Tetradecenoylcarnitine (C14:1)

Decanoylcarnitine (C10)

Dodecanoylcarnitine (C12:0)

Free Carnitine (C0)

Octanoylcarnitine (C18:1)

Palmitoylcarnitine (C16)

Propionylcarnitine (C3)

Stearoylcarnitine (C18)

Tiglylcarnitine (C5:1)

Glutarylcarnitine (C5-DC) Total Carnitine

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

Scheme Organiser: MCA[†]

Lipids in serum[†] New for 2026!

Scheme Code: LIS

Aim: Comparison of the outcome of assays for various lipids in serum relevant to the diagnosis of inborn errors of metabolism, in respect to median and target values.

Status: Running as a full EQA scheme for the first time in 2026 (previously ran as a pilot scheme in 2024 and 2025).

Analytes (2026): 7-dehydrocholesterol (7-DHC) Lathosterol

7-ketocholesterol (7-KC) Lyso-globotriaosylceramide (Lyso-Gb3)
C26:0-lysophospatidylcholine (C26:0-lysoPC) Lyso-monosialoganglioside 1 (Lyso-GM1)
Cholestane-3β,5α,6β-triol Lyso-monosialoganglioside 2 (Lyso-GM2)

Cholestanol Lyso-sphingomyelin (Lyso-SM)

Coenzyme Q10 N-palmitoyl-O-phosphocholineserine (PPCS)

Desmosterol Sitosterol

Glucosylsphingosine

Non-scoring analytes[‡]: Cholesterol

Scientific Advisor: Dr Susanna Goorden, admin@erndim.org

Scheme Organiser: MCA[†]

[‡] Non-scoring analytes are present in the matrix so results can be recorded for comparison between labs <u>BUT</u> the concentrations do not vary. As a result, they do not contribute to performance evaluation, and are not included in the Individual Online Annual Reports or Certificates of Participation.

^{*} Full details of the scheme design for each of the Quantitative schemes are given in section 2.1.1 on page 7.



Scheme Code: PPU

Purines and Pyrimidines (urine)†

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

Status: Full EQA scheme since 2000.

5-OH Methyluracil Deoxy-adenosine Hypoxanthine Uracil Analytes (2026):

3-Ureidoisobutyric acid Deoxy-guanosine Inosine Uridine 3-Ureidopropionic acid Deoxy-inosine Orotic acid Xanthine

Adenine Deoxy-uridine Pseudo-uridine Adenosine Dihydro-thymine Succinyl adenosine

AICAriboside Dihydro-uracil **Thymidine Thymine** Cytidine Guanosine

Non-scoring analytes‡: Creatinine (mmol/L), Uric acid

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

Scheme Organiser: MCA[†]

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.

2-Aminobutyric acid Cystine Lysine **Taurine** Analytes (2026):

Alanine Glutamic acid Methionine Threonine Ornithine Allo-isoleucine Glutamine Tryptophan Glycine Phenylalanine Tyrosine **Arginine** Proline Valine Argininosuccinic acid Histidine

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

N-acetylaspartic acid

Pyroglutamic acid Sebacic acid

Suberic acid

Tiglylglycine

Suberylglycine

Vanillactic acid

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

Status: Full EQA scheme since 1993.

2-Methylcitric acid Adipic acid Mevalonic acid Analytes (2026):

> 2-OH-Glutaric acid Ethylmalonic acid 3-Methylglutaconic acid Fumaric acid 3-Methylglutaric acid Glutaric acid 3-OH-3-Methylglutaric acid Hexanoylglycine 3-OH-Butyric acid Isovalerylglycine 3-OH-Glutaric acid Keto-glutaric acid 3-OH-Isovaleric acid Malic acid 3-OH-Propionic acid Malonic acid

4-OH-Butyric acid Methylmalonic acid

Non-scoring analytes[‡]: Creatinine (mmol/L)

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

Scheme Organiser: MCA[†]

[‡] Non-scoring analytes are present in the matrix so results can be recorded for comparison between labs <u>BUT</u> the concentrations do not vary. As a result, they do not contribute to performance evaluation, and are not included in the Individual Online Annual Reports or Certificates of Participation.

[†] Full details of the scheme design for each of the Quantitative schemes are given in section 2.1.1 on page 7.



Scheme Code: SADB

Scheme Code: SAU

Special Assays in dried blood spots[†]

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 (2026): Allo isoleucine Methionine Tyrosine

Isoleucine NTBC (nitisone) Valine

Leucine C0 free carnitine Phenylalanine

L-Homocysteine Succinylacetone

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

Scheme Organiser: MCA[†]

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.

Status: Full EQA scheme since 1993.

Cholestanol Analytes* (2026): 3 OH Butyric acid Methylmalonic acid

> 7-Dehydrocholesterol Creatine Phytanic acid C22:0 Behenic acid Galactose Pipecolic acid C24:0 Lignoceric acid Guanidineacetic acid Pristanic acid C26:0 Cerotic acid Homocysteine Pyruvic acid Carnitine Free Lactic acid Succinylacetone

Non-scoring analytes[‡]: Biotinidase, Cholesterol, FGF21, GDF15, NEFA

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

Scheme Organiser: MCA[†]

Special Assays in Urine[†]

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.

Status: Full EQA scheme since 1993.

Analytes (2026): 4-OH-Glutamic acid Glycolic Acid Orotic acid

> 5-Aminolevulinic acid Guanidineacetic acid Oxalic acid

5-OH-Indolacetic acid Homocitrulline Phosphoethanolamine

Carnitine Free Pipecolic acid Homogentisic acid Creatine Homovanillic acid (HVA) Sialic acid Creatinine Lactic acid Succinylacetone D,L-Glyceric acid L-Cystine Sulfocysteine

Galactitol MPS (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).

^{*} Note for 2026, some lipid analytes have moved from the SAS scheme to the LIS scheme, see Page 4.

[‡] Non-scoring analytes are present in the matrix so results can be recorded for comparison between labs <u>BUT</u> the concentrations do not vary. As a result, they do not contribute to performance evaluation, and are not included in the Individual Online Annual Reports or Certificates of Participation.

[†] 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.

	ACS	LIS	PPU	QTAS	QTOU	SADB	SAS	SAU				
Detailed scheme information on page:	p4	p4	p5	p5	р5	p6	p6	p6				
General												
Eligibility Requirements:	Participa	nts must p	roduce the	r own resu	ılts and can	not send sampl	es to a sub-co	ntracted (or				
ů ,	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 129 56** 52 276 136 121 277 212										
No. of registrations (2025):	129											
Geographic area:					Worldwide							
Sample volume/vial	0.5ml	1ml	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			Yes					
Lyophilised urine			Yes		Yes			Yes				
Sample treated with gentamicin	No Yes No											
Scheme Design												
Sample design/selection:			5	Scientific A	dvisor for ea	ach scheme						
Sample manufacture subcontracted to:					MCA							
Sample aliquoting subcontracted to:					MCA							
Sample Dispatch subcontracted to:					ne dispatch							
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					Vaa							
submission deadline	Yes											
Scheme Annual Reports (AR)	published in Jan-Mar of the following year											
Full anonymised scheme results included in AR			•		No	<u> </u>						

^{* =} For more information on Educational Participation see Section 5.7 of the Participants' Guide section of this catalogue on page 18;

^{** =} LIS was a pilot scheme in 2025.



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; <u>and</u> 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 Laboratories

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 Hybrid schemes.

Cystine in White Blood Cells^{††}

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 (2026): 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

Scheme Code: CWBC

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

Status: Full EQA scheme since 2011.

Expected Enzymes alpha-fucosidase beta-galactosidase

(2026): alpha-galactosidase beta-glucosidase alpha-glucosidase beta-glucuronidase alpha-mannosidase heparan-N-sulphatase

aspartylglucosaminidase N-acetylglucosamine-6-sulphatase

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 (2026): 3-methyl dopa (3-MD) Biopterin

5-OH-Indolacetic acid (5-HIAA) Homovanillic acid (HVA) 5-OH-Tryptophan (5-HTTP) HVA:5-HIAA ratio

5-methyltetrahydrofolic acid (5-MTHF) 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 (BH₄)

metabolism.

Status: Full EQA scheme since 2017.

Analytes (2026): Creatinine (mmol/L)

Neopterin (µmol/L & mmol/mol Creat)

Biopterin (µmol/L & mmol/mol Creat)

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

Primapterin (µmol/L & mmol/mol Creat)

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 2026 scheme calendar, see Section 3 on page 15.

	CWI	3C	LEFB	NCSF	PTU				
Detailed scheme information on page:	p8		p8	p8	р9				
General			P						
Eligibility Requirements:	Participants	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 (2025):	39)	72	38	32				
Geographic area:			Worldwic	le					
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:		Scienti	fic 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:			Netherlan		_				
No of samples/year:	8*	*	6	8	8				
Results Submissions			_						
No of submission deadlines/year:	8		2	8	8				
Submission of results:		online	e (ERNDIM-M	CA website)					
Quantitative results submission is mandatory Interpretation results submission is mandatory	Yes Yes								
			162						
Scoring of results: Analysis scored			Voc						
Diagnoses Scored	Yes Yes								
Reports:			Yes						
Interim Reports									
Published after each submission deadline (no. days)			21						
Individual Lab Annual Reports			۷1						
Published after the submission deadline	Ja	n	-	Jan	Jan				
Scheme Annual Reports (AR)		published in Jan-Mar of the following year							
Full anonymised scheme results included in AR	-		Yes	_	-				
,					1				

^{* =} For more information on Educational Participation see Section 5.7 of the Participants' Guide section of this catalogue on page 18;

^{** = 8} pairs of protein and WBC supernatants, 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 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 <u>previous</u> 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 Laboratories

For all Qualitative schemes, <u>except</u> 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 <u>not</u> allowed in any of the Qualitative schemes, except for the DPT scheme, and <u>participating laboratories must carry out</u> 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 diagnose inherited disorders resulting in recognisable patterns of amino acids in plasma and other specimens

tatus: 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 2026 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 (data only)

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

Scheme Organisers: ERNDIM, admin@erndim.org



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.

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

project. [ERNDIM allocates labs to a centre broadly based on geographical 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***



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^{†††}



2.3.1. Qualitative EQA Schemes' Design summary

Full details of the analyte groups included in each scheme can be found on pages 11 to 13. For the provisional 2026 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	PIL	Pii	PII	PIL	P I L	p.o				
Method Orientated scheme?	No Yes									
Method Orientated scheme:		See DDT								
Eligibility Requirements:	information Participants must produce their own results and cannot send									
11 61 6 1 1 11 11	011 p 12									
Use of cluster labs allowed?	Yes		No Yes							
Educational participation allowed? ¹ No of organising centres:	No 5	1	3	<u>r</u>	3	1				
No or organising centres.		ı				Į.				
No. of registrations (2025):	95 (15-21 per centre)	148	142 (46-49 per centre)	57	234 (77-79 per centre)	89				
Geographic area:			World	dwide						
EQA Samples										
Sample volume/vial:	5-10ml	n/a	30-50µl	25 µl ²	2-3 ml/vial	5ml				
Sample type	Clinical samples	Data from clinical samples			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		Scie	entific Advisors (SA) for each sch	neme					
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 ³	n/a	Switzerland ³	Netherlands	Switzerland ³	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	No Yes							
Analysis of data samples only	No	Yes			lo					
Interpretation, including diagnoses			Y	es						
Reports:										
Interim Reports										
Published 8-10 weeks after the submission deadline	n Yes									
Diagnoses circulated by email 2-3 weeks after submission deadline	Vec									
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									
i un anonymiseu soneme results included ili AR	Yes									

¹ = For more information on Educational Participation see Section 5.7 of the Participants' Guide section of this catalogue on page 18;

² = see CDG scheme information on page 12.

³ = For Italy and Spain, the sample parcel will be dispatched from the Netherlands



3. 2026 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 2026, will be updated with confirmed dates as they become available.

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

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



4.2026 Price List



		2026 Prices				
EQA Schemes	Scheme Code	Euro	GB Pounds	US\$		
1. Quantitative Schemes						
Acylcarnitines in Serum	ACS	442	399	521		
Lipids in Serum	LIS	246	222	290		
Purines and Pyrimidines (urine)	PPU	491	443	579		
Quantitative Amino Acids (serum)	QTAS	391	353	461		
Quantitative Organic Acids (urine)	QTOU	466	420	549		
Special Assays in Dried Blood Spots	SADB	323	291	382		
Special Assays (serum)	SAS	254	229	300		
Special Assays (urine)	SAU	240	217	283		
Special Assays Combined (serum & urine)	SAC	442	399	521		
2. Hybrid Schemes						
Cystine in White Blood Cells	CWBC	484	437	571		
Lysosomal Enzymes (fibroblasts)	LEFB	834	753	984		
Neurotransmitters (CSF)	NCSF	487	440	574		
Pterins in Urine	PTU	472	426	557		
3. Qualitative Schemes						
Acylcarnitines (dried blood spots) *	ACDB	442	399	521		
Amino Acids Interpretation	AAI	177	150	180		
Congenital Disorders of Glycosylation (serum) *	CDG	452	408	533		
Diagnostic Proficiency Testing (urine) *	DPT	630	569	743		
Qualitative Organic Acids (urine) *	QLOU	475	429	560		
Urine Mucopolysaccharides *	UMPS	423	382	499		
Mailing fee per scheme for	41	36	48			

Please note:

- VAT at 20% will be added to invoices for all UK laboratories.
- The mailing fee <u>per scheme</u> will be 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 <u>previous</u> 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 2026 EQA schemes, registration will be open from mid-September to late-October 2025 (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 <u>ERNDIM Privacy Policy</u> on <u>www.erndim.org</u>, 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 <u>must not</u> 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 <u>must</u> contact the Administration Office to obtain permission <u>before</u> 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.

5.4.1. Use of ERNDIM data to train Al

In all cases, the use of any ERNDIM related data for training artificial intelligence systems is <u>strictly prohibited</u>. ERNDIM data includes, but is not limited to, data derived from the use or analysis of ERNDIM EQA materials, or present in any ERNDIM scheme or other reports.

5.5. EQA participation fees

The price list for the 2026 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 2026 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 schemes.

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 <u>EQA schemes</u> 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 <u>ERNDIM website</u> <u>under EQA schemes</u>. 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. In addition, the use of this data for training artificial intelligence systems is strictly prohibited. See item 5.4 for details.

If a laboratory does not submit results, or submits insufficient results for performance to be assessed this will be shown on the Certificate of Participation. If this occurs in multiple years, 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 <u>before</u> 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 <u>admin@erndim.org</u> as soon as possible.

However, please note that <u>result</u> <u>submission</u> <u>extensions</u> <u>will only be granted under **exceptional** <u>circumstances</u> and no late/amended results can be accepted if the relevant consensus results or diagnoses have already been published.</u>

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. In addition, the use of this data for training artificial intelligence systems is strictly prohibited. See item 5.4 for details.

5.13. Performance Assessment

Submitted results are evaluated according to ERNDIM policies and procedures. The frameworks for assessment for each scheme type can be found on the Participant Information tab of the Registration Website (www.eqa.erndim.org) under Assessment and Education.

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.

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.

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

<u>Unfortunately payments by cheque cannot be accepted.</u>

ERNDIM bank accounts.

For payments in <u>Euros</u> 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 <u>GB Pounds</u> 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



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

Use of data derived from ERNDIM EQA Materials

- 1. <u>Data derived from the use or analysis of ERNDIM EQA</u> materials **must not be** used in written publications or oral presentations unless the explicit prior consent of ERNDIM has been granted.
 - If a participating laboratory wishes to use such data in a publication or presentation, they <u>must</u> contact the ERNDIM Administration Office before submitting any documents for publication.
 - 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.
- 2. <u>Use of ERNDIM data to train artificial (AI) intelligence systems</u>
 - The use of any ERNDIM related data for training Al systems is strictly prohibited. ERNDIM data includes, but is not limited to, data derived from the use or analysis of ERNDIM EQA materials, or present in any ERNDIM scheme or other reports.

Registering for EQA Schemes

- 3. 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:
 - Email and postal addresses for a primary and secondary contact persons* (these contacts will be used for all routine ERNDIM correspondence)
 - 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 contacts persistently do not respond to ERNDIM correspondence)
 - 3. A postal address for the registering Laboratory
 - 4. A delivery address for EQA materials
 - 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.

- 4. 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.
- 5. 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.
- 6. 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.

Invoices and Payments

- 7. If your hospital or laboratory procedures require a Purchase Order number on the invoice, this should be added to the registration form.
- 8. 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.
- 9. 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.
- 10. 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.
- 11. 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.
- 12. It is the responsibility of the participant laboratory to ensure that the ERNDIM invoice is paid.
- 13. 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.
- 14. ERNDIM is responsible solely for paying its own bank charges. Any other charges related to invoice payments must be paid by the participant.
- 15. Penalties for late payment of invoices are:
 - 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 will be generated;
 - 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

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



- 17. Compliance with the EQA submission deadlines is a requirement of satisfactory participation in the EQA schemes.
 - 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.
 - No late/amended results can be accepted if the relevant consensus results or diagnoses have already been published.
- 18. 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).
 - 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.
 - 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.
- 19. All participating laboratories are given a unique ERNDIM reference number which should be used on all invoice payments and in all correspondence with ERNDIM.
- 20. 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.
 - 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

- 21. Satisfactory performance in an EQA scheme is based solely on the laboratory's performance when analysing the EQA 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).
- 22. ERNDIM is not responsible for the performance of participating laboratories when offering a clinical diagnostics service.
- 23. 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.

- 24. 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.
- 25. 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.
- 26. 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

- 27. 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.
- 28. By using this website, you consent to ERNDIM processing any data you provide in line with the <u>ERNDIM Privacy Policy</u> 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

29. 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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30. 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.