ERNDiM

Quality Assurance in Laboratory Testing for IEM

# EQA Schemes Catalogue and Participant Guide 2023

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# Contents



| Version Date | Amendments |
|---|---|
| 07 September 2022 | • 2023 EQA Catalogue published |
| 10 January 2023 | • Page 4, PPU scheme: SAICAriboside removed from list of analytes |
| 13 March 2023 | • Page 5, QTAS scheme: Homocitrulline removed from list of analytes |
| | |

# 1. Introduction

ERNDIM is an independent not-for-profit foundation which has been providing External Quality Assurance (EQA) schemes in the field of inborn errors of metabolism since 1994. While originally a European organisation we now have over 400 participants from 62 countries, with approximately 60% of our participants coming from outside of Europe in 2022.

In 2023 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 2022 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 2023 EQA schemes has opened, they will need to accept these terms and conditions before they will be able to submit their EQA order. If you have any questions about the terms and conditions, please contact admin@erndim.org.

# 2. EQA Schemes

## 2.1. Quantitative EQA Schemes

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

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

### Cluster Labs

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

### Acylcarnitines in serum† — Scheme Code: ACS

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

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

**Analytes (2023):**

| | |
|---|---|
| 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 (2023):**

| | | |
|---|---|---|
| 5-OH Methyluracil | Deoxy-guanosine | Orotidine |
| 3-Ureidoisobutyric acid | Deoxy-inosine | Pseudo-uridine |
| 3-Ureidopropionic acid | Deoxy-uridine | Succinyl adenosine[2] |
| Adenine | Dihydro-thymine | Thymidine |
| Adenosine | Dihydro-uracil | Thymine |
| AICAriboside | Guanosine | Uracil |
| Creatinine (mmol/L)[1] | Hypoxanthine | Uric acid[1] |
| Cytidine | Inosine | Uridine |
| Deoxy-adenosine | Orotic acid | Xanthine |

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

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

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

**Scheme Organiser:** MCA†

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

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

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

**Status:** Full EQA scheme since 1993

**Analytes[3] (2023):**

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

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

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

**Scheme Organiser:** MCA[†]

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

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

**Status:** Full EQA scheme since 1993

**Analytes (2023):**

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

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

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

**Scheme Organiser:** MCA[†]

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

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

**Status:** Full EQA scheme since 2019

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

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

**Analytes (2023):**

| | | |
|---|---|---|
| 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 (number of samples, submission deadlines, subcontracted activities etc.) for each of the Quantitative schemes are given in section 2.1.1 on page 7.*

## Special Assays in Serum[†] — Scheme Code: SAS

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

**Status:** Full EQA scheme since 1993

**Analytes (2023):**

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

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

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

**Scheme Organiser:** MCA[†]

## Special Assays in Urine[†] — Scheme Code: SAU

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

**Status:** Full EQA scheme since 1993

**Analytes (2023):**

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

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

**Scheme Organiser:** MCA[†]

## Special Assays Combined — Scheme Code: SAC

If you wish to order both the Special Assays in Serum and Special Assays in Urine scheme please select 'Special Assays Combined (serum + urine)' when submitting your order on the registration website and a discount for ordering both schemes will be applied to your order (see the EQA scheme price list on page 16).

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

## 2.1.1. Quantitative EQA Schemes' summary

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

| 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 | No | No | No | No | No | No |
| No. of registrations (2022): | 127 | 56 | 285 | 133 | 112 | 268 | 213 |
| Geographic area: | Worldwide | | | | | | |
| **Sample volume/vial** | 0.5ml | 2.5ml | 1ml | 5ml | 75 µl initial blood volume | 5ml | 5ml |
| Matrix of human origin, spiked with commercially available analytes | Yes | | | | | | |
| **Matrix:** | | | | | | | |
| Dried blood spots | | | | | Yes | | |
| Lyophilised plasma/serum | Yes | | Yes | | | Yes | |
| Lyophilised urine | | Yes | | Yes | | | Yes |
| **Scheme Design** | | | | | | | |
| Sample design/selection: | Scientific Advisor for each scheme | | | | | | |
| Sample manufacture subcontracted to: | MCA | | | | | | |
| Sample aliquoting subcontracted to: | MCA | | | | | | |
| Sample Dispatch subcontracted to: | MCA: one dispatch per year | | | | | | |
| Country samples will be dispatched from: | Netherlands | | | | | | |
| No of samples/year: | 8 | | | | 8 EQA samples and 8 additional DBS[6] | 8 | |
| **Results Submissions** | | | | | | | |
| No of submission deadlines/year: | 8 | | | | | | |
| Submission of results: | online (ERNDIM-MCA website) | | | | | | |
| **Scoring of results:** | | | | | | | |
| Analysis scored | Yes | | | | | | |
| **Reports:** | | | | | | | |
| **Interim Reports** | | | | | | | |
| Published 14 days after each submission deadline | Yes | | | | | | |
| **Individual Lab Annual Reports** | | | | | | | |
| Published 14 days after the last submission deadline | Yes | | | | | | |
| Full anonymised scheme results included in AR | No | | | | | | |
| **Scheme Annual Reports (AR)** | published in Jan-Feb of the following year | | | | | | |

[6] = see SADB scheme information on page 5

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

## 2.2. Hybrid EQA Schemes

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

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

**Cluster Labs**

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

### Cystine in White Blood Cells†† — Scheme Code: CWBC

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

**Status:** Full EQA scheme since 2005

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

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

**Sample matrix:** Protein is lyophilised, WBC supernatants are liquid

**Analytes (2023):** Cystine (nmol/aliquot) (250 µL SNT sample)
Protein(mg/pellet) (PP sample)
Cystine (nmol 1/2 cys/mg protein, calculated as if isolated from one 5 mL blood sample)

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

**Scheme Organiser:** MCA††

### Lysosomal Enzymes (fibroblasts)†† — Scheme Code: LEFB

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

**Status:** Full EQA scheme since 2011

**Expected Analytes (2023):**

- Alpha-Galactosidase
- Alpha-Glucosidase
- Alpha-Iduronidase
- Arylsulphatase A
- Beta-Galactosidase
- Beta-Glucosidase
- Galactose-6-sulphatase
- Hexosaminidase A + B
- Heparan-N-sulphatase
- Iduronate sulphatase
- Protein

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

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

**Scheme Organiser:** MCA††

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

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

**Status:** Full EQA scheme since 2016

**Analytes (2023):**

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

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

**Scheme Organiser:** MCA††

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

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

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

**Status:** Full EQA scheme since 2017

**Analytes (2023):**
- Creatinine (mmol/L)
- Biopterin (µmol/L & mmol/mol Creat)
- Neopterin (µmol/L & mmol/mol Creat)
- Primapterin (µmol/L & mmol/mol Creat)

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

**Scheme Organiser:** MCA[††]

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

## 2.2.1. Hybrid EQA Schemes' summary

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

| Detailed scheme information on page: | CWBC<br>p8 | LEFB<br>p8 | NCSF<br>p8 | PTU<br>p9 |
|---|---|---|---|---|
| **General** | | | | |
| Eligibility Requirements: | Participants must produce their own results and cannot send samples to a sub-contracted (or cluster) laboratory | | | |
| Use of cluster labs allowed? | No | | | |
| No. of registrations (2022): | 39 | 72 | 38 | 37 |
| Geographic area: | Worldwide | | | |
| **EQA Samples** | | | | |
| **Sample volume/vial** | 5ml[7] | 0.5 mg lyophilised protein | 0.5ml | 1ml |
| **Sample type** | | | | |
| Artificial/human matrix spiked with commercially available analytes | | | Yes | |
| Clinical samples | | Yes | | |
| Matrix of human origin, spiked with commercially available analytes | Yes | | | Yes |
| **Matrix:** | | | | |
| Lyophilised cerebrospinal fluid | | | Yes | |
| Lyophilised fibroblasts | | Yes | | |
| Lyophilised urine | | | | Yes |
| White blood cells* | Yes[7] | | | |
| **Scheme Design** | | | | |
| Sample design/selection: | Scientific Advisor for each scheme | | | |
| Sample manufacture subcontracted to: | MCA | CHU Lyon | MCA | University Children's Hospital, Zurich |
| 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[7] | 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 | No | Yes | Yes |
| Diagnoses Scored | Yes | | | |
| **Reports:** | | | | |
| **Interim Reports** | | | | |
| Published 14 days after each submission deadline | Yes | | | |
| **Individual Lab Annual Reports** | | | | |
| Published 21 days after the last submission deadline | Yes | No | Yes | Yes |
| Full anonymised scheme results included in AR | - | Yes | - | - |
| **Scheme Annual Reports (AR)** | published in Jan-Feb of the following year | | | |

[7] = 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 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: Dr Charles Turner, 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)

**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 2023 is limited to 100, 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 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

## 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†††

## 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 detail of the analyte groups included in each scheme can be found on pages 11 to 13.

| Detailed scheme information on page: | DPT<br>p12 | AAI<br>p11 | ACDB<br>p11 | CDG<br>p12 | QLOU<br>p12 | UMPS<br>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 | | | | |
| No of organising centres: | 5 | 1 | 3 | 1 | 3 | 1 |
| No. of registrations (2022): | 102 (19-21 per centre) | 105 [pilot scheme] | 132 (42-46 per centre) | 67 | 222 (73-75 per centre) | 87 |
| Geographic area: | Worldwide | | | | | |
| **EQA Samples** | | | | | | |
| Sample volume/vial: | 5-10ml | n/a | 30-50µl | 25 µl[8] | 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 | | Yes | | | |
| Analysis of data samples only | | Yes | | | | |
| Interpretation, including diagnoses | Yes | Yes | 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 | No | Yes | No | Yes | Yes |
| Full anonymised scheme results included in AR | Yes | | | | | |
| **Scheme Annual Reports (AR)** | published in Jan-Feb of the following year | | | | | |

[8] = see CDG scheme information on page 12

## 3. 2023 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 2023, 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<br>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. 2023 Price List

| EQA Schemes | Scheme Code | 2023 Prices Euro | GB Pounds | US$ |
|---|---|---|---|---|
| **1. Quantitative Schemes** | | | | |
| Acylcarnitines in serum | ACS | 375 | 338 | 442 |
| Purines and Pyrimidines (urine) | PPU | 416 | 375 | 491 |
| Quantitative Amino Acids (serum) | QTAS | 332 | 299 | 391 |
| Quantitative Organic Acids (urine) | QTOU | 395 | 356 | 466 |
| Special Assays in dried blood spots | SADB | 274 | 247 | 323 |
| Special Assays (serum) | SAS | 215 | 194 | 254 |
| Special Assays (urine) | SAU | 204 | 184 | 240 |
| Special Assays Combined (serum & urine) | SAC | 375 | 338 | 442 |
| **2. Hybrid Schemes** | | | | |
| Cystine in White Blood Cells | CWBC | 411 | 371 | 484 |
| Lysosomal Enzymes (fibroblasts) | LEFB | 707 | 639 | 834 |
| Neurotransmitters (CSF) | NCSF | 413 | 373 | 487 |
| Pterins in Urine | PTU | 400 | 361 | 472 |
| **3. Qualitative Schemes** | | | | |
| Acylcarnitines (dried blood spots) * | ACDB | 375 | 338 | 442 |
| Amino Acids Interpretation | AAI | 150 | 127 | 153 |
| Congenital Disorders of Glycosylation (serum) * | CDG | 383 | 346 | 452 |
| Diagnostic Proficiency Testing (urine) * | DPT | 534 | 482 | 630 |
| Qualitative Organic Acids (urine) * | QLOU | 403 | 364 | 475 |
| Urine Mucopolysaccharides * | UMPS | 359 | 324 | 423 |
| **Mailing fee per scheme for all laboratories:** | | **30** | **26** | **35** |

**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 2023 EQA schemes, registration will be open from **mid September to early November 2022**. In some circumstances late registration may be possible but will be dependent upon sample availability and the

agreement of the relevant Scientific Advisor.

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

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

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

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

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

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

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

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

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

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

**4.** **Submit** your order.

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

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

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

## 5.2. Terms & Conditions of EQA scheme registration

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

performance (which may include sharing information between the ERNDIM schemes that you subscribe to), unless ERNDIM is required to disclose performance data by a relevant government agency.

Please see the terms and conditions on page 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 2023 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 Training/Grants.

Applications for support during the 2023 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.erndim.org/qa) under Participant Information. There is one form for the qualitative schemes and separate forms for each of the quantitative and hybrid schemes.

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

## 5.8. Sample Donation

Several of the ERNDIM EQA schemes use real clinical samples as the EQA materials however, it is becoming increasingly difficult to source suitable clinical samples. Details of the types of samples that would be useful to ERNDIM can be found on the EQA 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 3-6 weeks before sample dispatch.

### 5.10.1. Replacement Samples

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

## 5.11. Analysis and Reporting

You will receive instructions on sample testing and reporting processes with the sample shipments. Scheme instructions will also be available to download from the ERNDIM Registration website (www.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 in writing to the ERNDIM Administration Office within 4 weeks of the date of the performance support letter.

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

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

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

### 5.16.2. Complaints

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

### 5.16.3. Feedback to ERNDIM

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

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

## 5.17. Subcontracted Activities

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

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

the EQA schemes tab of the ERNDIM website (www.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/Grants.

## 5.19. Invoicing & Payment Information

### 5.19.1. Invoices

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

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

If you receive a purchase order number from your

finance department after the Registration period has closed, please send it to the Administration Office as soon as possible so it can be added to your invoice.

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

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

Invoices show:

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

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

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

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

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

Late payment will incur penalties as specified below:

- Interest charges of 1.3% per month are applied to outstanding balances after the invoice payment date. When interest is added to the outstanding balance an updated invoice with a new version number will be sent to the participant.
- If there is still an outstanding invoice balance after the 1st July, in the next year the invoice payment date will be 31st January and the dispatch of samples to the laboratory in that year will be delayed until ALL outstanding invoices have been paid.
- If there is still an outstanding invoice balance after the 1st August, access to the EQA scheme

results will be restricted until the invoice has been paid.

- If there is still an outstanding invoice balance after the 1st September, in the same year as the scheme participation, the laboratory will not be eligible to register for any ERNDIM EQA schemes until all outstanding invoices have

been paid and a Certificate of Participation for the current year will not be issued.

### 5.19.2. Payment Information

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

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

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

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

**ERNDIM bank accounts.**

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

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

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

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

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

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

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

### Use of data derived from ERNDIM EQA Materials

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

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

### Registering for EQA Schemes

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

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

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

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

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

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

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

### Invoices and Payments

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

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

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

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

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

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

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

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

14. Penalties for late payment of invoices are:

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

## EQA Scheme Participation

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

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

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

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

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

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

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

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

## Performance Evaluation

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

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

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

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

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

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

## Data Protection & Privacy

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

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

## Problems & Complaints

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

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