ERNDIM
Quantitative Schemes
Special Assays in Urine

ANNUAL REPORT 2025

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1. *Purpose*

The purpose of the ERNDIM External Quality Assurance Scheme for Special Assays in Urine is the monitoring of the analytical quality of the quantitative assay of a range of analytes in urine in laboratories involved in the diagnosis of patients with inherited metabolic disorders. For details see www.erndimqa.nl

2. *Participants*

A total of 244 datasets (190 labs) have been submitted, for 4 of them an annual report could not be generated due to insufficient data submission. 4 laboratories did not submit results at all.

3. *Design*

The Scheme has been designed, planned and coordinated by the scientific advisor Dr. Rafael Artuch and Dr. R.M. Schoeman as scheme organizer (on behalf of MCA laboratory), both appointed by and according to the procedures of the ERNDIM Board. The design includes samples and reports to provide information with a balance between short-term and long-term reports and between detailed and aggregated information. As a subcontractor of ERNDIM, the MCA Laboratory prepares and distributes the EQA samples to the scheme participants and provides a website for on-line submission of results and access to scheme reports.

[1] If this Annual Report is not Version 1 for this scheme year, go to APPENDIX 1 for details of the changes made since the last version of this document.

Samples

The scheme consisted of 8 lyophilised samples, all prepared from the same basic urine but with various amounts of added analyte. The samples were identical two by two: the pairs, analytes, and their source, as well as the added amounts, are in the table below. Samples have been tested for stability and homogeneity according to ISO 13528, and are stable for the duration of the scheme's submission calendar when stored under defined conditions.

Table 1.

Analyte	Source:	Units	Added Amounts			
			Sample Pair 2025. 01 - 08	Sample Pair 2025. 02 - 07	Sample Pair 2025. 03 – 06	Sample Pair 2025. 04 – 05
4-OH-Glutamic acid	Sigma 76157	µmol/L	12.0	25.2	0.0	49.8
5-Aminolevulinic acid	Sigma A3785	µmol/L	5.5	14.9	0.0	29.6
5-OH indolacetic acid	Sigma H8876	µmol/L	28.1	58.3	97.8	12.9
Carnitine free	Sigma C0283	µmol/L	335.9	1.6	136.7	486.2
Creatine	Sigma C3630	µmol/L	0.0	2000.0	1500.8	500.1
Creatinine	Sigma C6257	mmol/L	5.0	1.5	0.0	3.0
D,L-Glyceric acid	BioConnect SC-294396	µmol/L	280.1	928.9	140.0	0.0
Galactitol	Sigma D0256	µmol/L	195.8	46.1	121.1	296.0
Glycolic acid	Sigma G8284	µmol/L	124.3	0.0	49.6	201.7
Guanidinoacetate	Sigma G11608	µmol/L	1.2	966.2	466.7	166.1
Homocitrulline	BioConnect SC-269298	µmol/L	0.0	2.0	10.1	5.1
Homogentisic acid	Sigma H0751	µmol/L	99.9	500.1	0.0	1000.1
Homovanillic acid	Sigma H1252	µmol/L	97.0	26.9	12.1	56.9
Lactic acid	Sigma L7022	mmol/L	2.9	5.7	8.9	0.0
L-Cystine	Sigma C8755	µmol/L	199.9	300.0	100.1	0.0
MPS (Chondroitin sulfate)	Sigma C6737	mg/L	97.0	17.0	47.1	147.0
Orotic acid	Sigma O2750	µmol/L	2.4	98.8	58.9	29.2
Oxalic acid	Sigma O0136	µmol/L	478.1	78.2	0.0	277.9
Pipecolic acid	Sigma P2519	µmol/L	19.5	29.8	40.0	2.2
Sialic acid	Sigma A2388	µmol/L	200.1	0.0	125.1	100.0
Succinylacetone	Sigma D1415	µmol/L	50.0	0.6	5.0	149.9
Sulfocysteine	Sigma C2196	µmol/L	32.9	10.1	3.0	19.8

Reports

All data-transfer, the submission of data as well as the request of reports proceeded via the interactive website www.erndimqa.nl which can also be reached through the ERNDIM website (www.erndim.org). The results of your laboratory are confidential and only accessible to you (with your name and password). The anonymised mean results of all labs are accessible to all participants. Statistics of the respective reports are explained in the general information section of the website.

An important characteristic of the website is that it supplies short-term and long-term reports. Short-term reports associated with the four individual specimens are available two weeks after the submission deadline and provide up-to-date information on analytical performance. Although it is technically possible to produce reports immediately, there is a delay of 14 days to enable the scientific advisor to inspect the results and add comments to the report when appropriate.
The annual report is based on the design-anchored connection between samples which enables a range of analytical parameters (accuracy, precision, linearity, recovery, and inter-lab dispersion) to be reported once the annual cycle has been completed.

A second important characteristic of the website is the wide range in aggregation of results which permits labs to make an individual choice for detailed and/or aggregated reports. The most detailed report which can be requested from the website is the "Analyte in Detail" which shows results of a specific analyte in a specific sample (176 such Analyte-in-Detail-reports can be requested in the 2025 cycle). A more condensed report in the "Cycle Review" which summarizes the performance of all analytes in a specific sample (8 such Cycle-Review-Reports can be requested in 2025). The highest degree of data aggregation can be found in the Annual Report which summarises the performance of all analytes from all 8 samples (1 such Annual-Report can be requested in 2025).

4. Discussion of Results in the Annual Report 2025

In this part the results as seen in the annual report 2025 will be discussed. Subsequently we will regard accuracy, precision, linearity, recovery, interlab CV and cross-sectional relations. Please keep at hand your annual report from the Interactive Website when you read the "guided tour" below and keep in mind that we only discuss the results of "all labs": it is up to you to inspect and interpret the specific results of your laboratory.

4.1 Accuracy

A first approach to describe accuracy is to compare the mean outcome of the eight samples in your lab with the mean of all labs. This is done in the first columns of the annual report. For example, it can be seen that for 5-OH-Indolacetic acid the mean outcome of all labs is 55.8 µmol/liter.

4.2 Precision

Reproducibility is an important parameter for quality in the laboratory and is encountered in the schemes' design. Samples come in pairs which can be regarded as duplicates from which CV's can be calculated (Intra Laboratory CV as indicator for reproducibility). Outcome for your lab in comparison to the median of all labs is shown in column "Precision" of the Annual Report. Precision ranges from 2.2% for Creatinine to 25.9% for Oxalic acid. The overall precision is a satisfying 9.9%.

4.3 Linearity

Linearity over the whole relevant analytical range is another important parameter for analytical quality. Again, this is encountered in the schemes' design. With weighed quantities on the x-axis and your measured quantities on the y-axis the coefficient of regression (r) has been calculated. Outcome for your lab in comparison to the median of all labs is in the column "Linearity" of the Annual Report. It can be seen that the coefficient of regression ranges from 0.934 for Oxalic acid to 0.998 for Creatine and Guanodinoacetate.

4.4 Recovery

A second approach to describe accuracy is the percentage recovery of added analyte. In this approach it is assumed that the recovery of the weighed quantities is the target value. The correlation between weighed quantities as added to the samples (on the x-axis) and your measured quantities (on the y-axis) has been calculated. The slope of the correlation multiplied with 100% is your recovery of added amounts. Outcome for your lab in comparison to median outcome of all labs is shown in the column "Recovery" in the Annual Report. For all labs the recovery ranges from 53% Oxalic acid to 107% for Sialic acid. The overall recovery is 93%.

4.5 *Interlab CV*

For comparison of outcome for one patient in different hospitals and for use of shared reference values it is relevant to have a high degree of harmonization between results of various laboratories. Part of the schemes' design is to monitor this by calculating the Interlaboratory CV. This, along with the number of laboratories who submitted results, is shown in the column "Data all Labs" in the Annual Report. It can be seen that most laboratories submitted results for Creatinine (128) whereas only 15 submitted results for 4-OH-Glutamic acid. The Interlab CV ranges from 4.91% for Creatinine to 54.5% for Oxalic acid.

4.6 *Cross Sectional Relations*

The various parameters as described above often have an interrelation: more than one parameter directs towards good or bad analytical control.
A typical example of good analytical control is Creatinine: many (128) laboratories submitted results, the reproducibility within the labs is good (precision of 2.2%), the Interlab CV is good with 4.91%, linearity is excellent (0.995) and recovery is 99%. Creatinine will be measured in many institutes by the general clinical chemistry lab using commercial analyzers. It is, therefore, not logical to compare it's results with those of chromatographic analyzers.

4.7 *Your performance: Flags*

In order to easily judge performance of individual laboratories, the annual report of an individual laboratory may include flags with different colours in case of poor performance for accuracy, precision, linearity and recovery. Analytes with satisfactory performance for at least three of the four parameters (thus no or only one flag) receive a green flag. Thus, a green flag indicates satisfactory performance for analysis of that particular analyte. Criteria for flags can be found in the general information on the website (on this website under general information; interactive website, explanation annual report).

4.8 *Poor Performance Policy*

A wide dispersion in the overall performance of individual laboratories is evident. Table 2 shows the percentage of flags observed. 55% of the laboratories have no flag at all and thus have attained excellent overall performance. In contrast, at the other extreme there are also 6% of laboratories with more than 25% red flags. Intensive discussion within the Scientific Advisory Board (SAB) has resulted in a harmonised scoring system that has been in place for the quantitative schemes for more than ten years; Likewise, there has been agreement as to what constitutes satisfactory performance. Both parameters are checked annually and, if necessary, re-evaluated. For further information, please refer to the Framework for Assessment and Education for Quantitative Schemes on our website (https://eqa.erndim.org/information/view/14). The ERNDIM Board has decided that the Scientific Advisor will judge the performance of the individual laboratories based on these levels of satisfactory performance and issue a letter of advice of failure to achieve satisfactory performance to those laboratories which do not achieve satisfactory performance. The letter is intended to instigate dialogue between the EQA scheme organiser and the participating laboratory in order to solve any particular analytical problems in order to improve quality of performance of labs in the pursuit of our overall aim to improve quality of diagnostic services in this field.

If your laboratory is assigned poor performance and you wish to appeal against this classification, please email the ERNDIM Administration Office (admin@erndim.org), with full details of the reason for your appeal, within one month receiving your

Performance Support Letter. Details of how to appeal poor performance are included in the Performance Support Letter sent to poor performing laboratories.

Table 2. Percentage Flags

% Red Flags seen in Annual Report	Percentage Labs In this Category	Cumulative Percentage Of Labs
>25%	6%	6%
25%	4%	10%
20 – 25%	3%	13%
15 – 20%	3%	16%
10 – 15%	10%	26%
5 – 10%	9%	35%
0 – 5%	10%	45%
0%	55%	100%

4.9 Certificates

Overall performance (as indicated by red/green flags in each laboratories annual report) is summarised in the annual participation certificate. The certificate lists the total number of special assays in the scheme, the number for which results have been submitted and the number for which satisfactory performance has been achieved. It is important to bear in mind that the certificate should be viewed in conjunction with the individual annual report in the case of internal or external auditing.

4.10 Additional Specific Remarks of the Scientific Advisor

The Annual Report, dealing with analytical performance in terms of accuracy, precision, linearity, recovery and inter-laboratory CV, shows a pattern similar to previous years. in general, the scheme shows a good performance. For 12 metabolites, the CV% among laboratories showed a value < 15%, for 2 between 15-20 and for 8 >20%. Oxalic acid showed the highest inter-laboratory CV (54.5%), followed by succinylacetone and 4-OH-Glutamic acid (in both, the interlab CV was slightly higher than 30% resp. 41.7% and 41.1%). Regarding homogentisic acid, participants performance moderately improved when compared with that of 2023, but same as 2024. Oxalic acid may have problems of solubility and precipitation should be avoided (53% of recovery).

5. Summary

The scheme shows in general, a good performance for the different parameters analysed.

6. Preview Scheme 2026

The design of the 2026 scheme is essentially the same as in 2025. Phosphoethanolamine is added in 2026.

7. Questions, Comments and Suggestions

If you have any questions, comments or suggestions please address to the scientific advisor of the scheme Mr. Rafael Artuch and/or to the scheme organiser Dr. R.M. Schoeman (mca.office@skbwinterswijk.nl).

Most complaints received by ERNDIM consist of minor misunderstandings or problems with samples, which can usually be resolved via direct contact with the ERNDIM administrative staff. If you wish to file a formal complaint, please email your complaint with details of your issue to admin@erndim.org or contact us through our website at https://www.erndim.org/contact-us/

Barcelona, 13th March 2026

Mr. Rafael Artuch
Scientific Advisor

Please note:
This annual report is intended for participants of the ERNDIM Special Assays in Urine scheme. The contents should not be used for any publication without permission of the scheme advisor.

The fact that your laboratory participates in ERNDIM schemes is not confidential. However, the raw data and performance scores are confidential and will be shared within ERNDIM for the purpose of evaluating your laboratory performance, unless ERNDIM is required to disclose performance data by a relevant government agency. For details, please see the terms and conditions in the ERNDIM Privacy Policy on www.erndim.org.

APPENDIX 1. **Change log (changes since the last version)**

Version Number	Published	Amendments
1	17th March 2026	• 2025 annual report published

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