





Product certificate ERNDIM IQCS Organic Acids

Product name Control Organic Acids

Product code	Product code	Colour cap
	ORG-02.1	Green
	ORG-02.2	Red

Date of issue 01-07-2018

Batch numbers and expiry date	Batch number	Exp. date stored at +2°C to +8°C
	 2018.1811	 2022-04
	 2018.1812	 2022-04

Reconstitution volume 10.0 mL

Estimated concentrations *

Analyte	Estimated concentrations (µmol/L)	
	Level 1	Level 2
2 Methylcitric acid	3	37
2 OH Glutaric acid	41	411
3 Methylglutaconic acid	19	97
3 Methylglutaric acid	7	49
3OH3 methylglutaric acid	38	320
3 OH Glutaric acid	8	33
3 OH Isovaleric acid	21	111
4 OH Butyric acid	14	152
Adipic acid	18	281
Creatinine	3000	6000
Ethylmalonic acid	19	240
Fumaric acid	9	209
Glutaric acid	16	225
Hexanoylglycine	4	29
Keto glutaric acid	34	552
Methylmalonic acid	15	220
Mevalonic acid	7	132
N acetylaspartic acid	22	351
Pyroglutamic acid	131	614
Sebacic acid	10	84
Tiglylglycine	14	60
Vanillactic acid	10	83
Isovalerylglycine	6	46
Suberic acid	14	185

* See ERNDIM Internal Quality Control System at the reverse

Organic Acids ERNDIM IQCS

Intended purpose

These materials are control materials (thus no calibrators) for the internal control of analytical systems for the determination of organic acids in urine.

Contents

Lyophilized human urine to which organic acids have been added to achieve an analytically and physiologically relevant level of the organic acids.

Storage and stability

The product in lyophilized form is stable for 5 years when stored at +2°C to + 8°C. Expiration dates are found on the product certificate (reverse). The stability of the reconstituted product is 48 hours when handled appropriately: pure water, replacement of stopper and storage at 2-8 °C.

Instructions for use

- a. Remove cap and stopper
- b. Add 10 mL aqua destillata
- c. Replace stopper
- d. Let stand for 15 minutes at room temperature
- e. Mix carefully during 20 minutes at room temperature
- f. Process product as patient sample

ERNDIM Internal Quality Control System: the Concept

The ERNDIM Internal Quality Control System (IQCS) consists of samples and a website for data management.

Samples

Samples contain analytes specifically selected for laboratories active in the field of inborn errors of metabolism. They come in two levels (1=low and 2=high) with for each analyte a relevant concentration.

Data Management

The website for data management is an extension of the website for the ERNDIM schemes and can be used to manage the laboratories internal quality control data (not obligatory; this is an option to serve ERNDIM users). Results are entered and a report can be requested showing the results of all analytes in the last run in comparison with

- a) the running mean of the lab,
- b) the running mean of all labs using the batch of internal control material and
- c) the acceptance limits set by the lab.

With a simple click on a specific analyte a classic Shewhart Chart appears showing the cumulative data of the lab. Details can be found under www.erndimqa.nl (see also remark 1).

Remarks

1. The ERNDIM IQCS will be implemented in steps between July 2018 and January 2020. The release of samples for organic acids (July 2018) will be a couple of months ahead of the availability of the website (estimated October 2018). Once the website is released all users will be informed that they can start using it.
2. On delivery of the control materials, the certificate in the package insert shows the values as measured by a peer laboratory. Once in use laboratories submit their results and the reports will show the trimmed mean of all laboratories. This mean is a running mean which changes with every new submission: Thus a dynamic assigned value resulting from "crowd targeting".

Precautions and warnings

1. For *in vitro* diagnostic use only.
2. This product should be handled with care, as appropriate for biological materials. Outdated and left-over material should be discarded as potentially infectious material, according to the procedures in your institute.

References

www.ERNDIMQA.nl

Dr C.W. Weykamp on behalf of the ERNDIM Internal Quality Control System Working Group

