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 15 October 2021

Batch numbers and expiry date

Batch number	Exp. date stored at +2°C to +8°C
LOT 2021.1471	**2026-07**
LOT 2021.1472	**2026-07**

Reconstitution volume 5.0 mL

Estimated concentrations *

Analyte	Estimated concentrations (µmol/L)	
	Level 1	Level 2
2 Methylcitric acid	1	32
2 OH Glutaric acid	28	279
3 Methylglutaconic acid	17	96
3 Methylglutaric acid	7	50
3OH3 methylglutaric acid	42	329
3 OH Glutaric acid	8	21
3 OH Isovaleric acid	9	76
4 OH Butyric acid	12	161
Adipic acid	16	259
Creatinine	3200	6000
Ethylmalonic acid	14	211
Fumaric acid	6	188
Glutaric acid	16	228
Hexanoylglycine	5	42
Isovalerylglycine	6	52
Keto glutaric acid	39	539
Methylmalonic acid	12	227
Mevalonic acid	7	132
N acetylaspartic acid	27	522
Pyroglutamic acid	151	625
Sebacid acid	12	103
Suberic acid	13	169
Tiglylglycine	17	68
Vanillacitic acid	23	151

* See ERNDIM Internal Quality Control System at the reverse

Consult Instructions For Use

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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.
b. Insert a hollow needle through the stopper to remove the vacuum (to prevent material getting on the stopper)
c. Remove stopper.
d. Add 5 mL aqua destillata
e. Replace stopper
f. Let stand for 15 minutes at room temperature
g. Mix carefully during 20 minutes at room temperature
h. 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
ERNDIM offers users of control materials a data management system (Note: this is an option to serve users; users do not have the obligation to use it). The strength of this system is that it does not only monitor the data of the laboratory but also compares the labs results with results of labs using the same batch of internal control materials.
In essence users can submit results every time they do an analytical run with the control material and then download two reports.
The Review Day Report shows the results of the last run in comparison to
a) the acceptance limits set by the lab,
b) the mean of all previous runs of the lab
c) the mean of all laboratories.
By clicking on the name of a specific analyte in the report, Shewhart charts of that analyte are shown.
The Cumulative Table report shows the cumulative data of the lab.

Details can be found under www.erndimqa.nl/General information/Use Website.

Remark
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 E.A.E. van der Hagen on behalf of the ERNDIM Internal Quality Control System Working Group