Product certificate ERNDIM IQCS Amino Acids

Product name Control Amino Acids

Product code

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

Date of issue 6 January 2021

Batch numbers and Expiry date

Batch number	Exp. date stored at +2°C to +8°C
LOT 2020.1291	**2025-11**
LOT 2020.1292	**2025-11**

Reconstitution volume 1.0 mL

Estimated concentrations *

Analyte	Estimated concentrations (µmol/L)	
	Level 1	Level 2
a-aminobutyric acid	26	90
Alanine	339	946
Arginine	24	529
Asparagine	38	211
Aspartic acid	16	106
Citrulline	19	424
Cystathionine	3	19
Cystine	27	64
Glutamic acid	67	242
Glutamine	531	1070
Glycine	308	1002
Histidine	104	403
Hydroxyproline	42	92
Isoleucine	32	397
Leucine	77	891
Lysine	84	519
Methionine	11	247
Ornithine	63	645
Phenylalanine	80	962
Proline	199	585
Sarcosine	ntd	ntd
Serine	55	469
Taurine	45	385
Threonine	104	415
Tryptophan	ntd	ntd
Tyrosine	51	898
Valine	157	825

ntd = not determined

* See ERNDIM Internal Quality Control System at the reverse

Consult Instructions For Use

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Amino Acids ERNDIM IQCS

Intended purpose
These materials are control material (thus no calibrators) for the internal control of analytical systems for the determination of amino acids in serum.

Contents
Lyophilized human serum to which amino acids have been added to achieve an analytically and physiologically relevant level of the amino 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 comparable to patient samples.

Instructions for use
a. Remove cap and stopper.
b. Add 1 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, i.e. it is advisable to immediately deproteinise samples and separate the supernatant to minimise stability problems of certain amino acids.
g. If not analysed on the same day according to your usual procedure for patient samples in your laboratory, the supernatant should be stored at -24ºC to -16ºC.

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. Tested and found negative for Hepatitis B Surface Antigen (HBsAg), antibody to hepatitis C (HCV), antibody to HIV and HIV antigen.
3. 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