





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 22 February 2024

Batch numbers and Expiry date	Batch number	Exp. date stored at +2°C to +8°C
	 2023.1471	 2028-10
	 2023.1472	 2028-10

Reconstitution volume 1.0 mL

Estimated concentrations *

Analyte	Estimated concentrations (µmol/L)	
	Level 1	Level 2
a-aminobutyric acid	34	97
Alanine	332	887
Arginine	28	531
Asparagine	44	248
Aspartic acid	22	132
Citrulline	21	433
Cystathionine	8	22
Cystine	32	58
Glutamic acid	67	247
Glutamine	660	1266
Glycine	316	915
Histidine	111	411
Hydroxyproline	42	96
Isoleucine	34	405
Leucine	82	885
Lysine	92	527
Methionine	11	249
Ornithine	71	619
Phenylalanine	84	929
Proline	199	587
Sarcosine	45	135
Serine	59	472
Taurine	58	442
Threonine	110	421
Tryptophan	139	322
Tyrosine	59	850
Valine	160	812

* See ERNDIM Internal Quality Control System at the reverse

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 -24°C to -16°C.

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](http://www.erndimqa.nl/General%20information/Use%20Website).

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

