Certificate of Analysis QCS Amino Acids

Product name Quality comparison material Amino Acids

Product code

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

Date of issue 23 March 2026

Batch numbers and Expiry date

Batch number	Exp. date stored at +2°C to +8°C
LOT 2025.1231	**2030-12**
LOT 2025.1232	**2030-12**

Reconstitution volume 1.0 mL

Estimated concentrations *

Analyte	Estimated concentrations (µmol/L)	
	Level 1	Level 2
a-aminobutyric acid	25	91
Alanine	321	840
Arginine	20	453
Asparagine	37	199
Aspartic acid	13	94
Citrulline	19	391
Cystathionine	12	38
Cystine	26	50
Glutamic acid	59	203
Glutamine	560	1058
Glycine	299	911
Histidine	98	357
Hydroxyproline	32	75
Isoleucine	26	362
Leucine	66	810
Lysine	80	464
Methionine	8	217
Ornithine	59	537
Phenylalanine	76	875
Proline	193	559
Sarcosine	44	116
Serine	45	424
Taurine	53	390
Threonine	98	373
Tryptophan	160	330
Tyrosine	52	818
Valine	145	757

Example

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Intended purpose
Not for diagnostic use.
This material is intended solely for the verification of the correct calibration of measurement methods. It is not permitted to use this material (without CE mark) in establishing or assessing patient/client results.

Disclaimer
It is the responsibility of the customer to limit the use of this material to the intended use described above. Streekziekenhuis Koningin Beatrix (department MCA laboratory) is not responsible or liable for application outside the intended use.

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. The expiration date is listed above. The stability of the reconstituted product is comparable to patient samples.

Instructions for use
a. Remove cap and stopper.
b. Add 1.0 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 Quality Comparison System: the Concept
The ERNDIM Quality Comparison System (QCS) 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 these 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 comparison materials.
In essence users can submit results every time they do an analytical run with the comparison 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 materials, the certificate in the package insert shows the values (estimated concentrations) 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* 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

Example