





Product certificate ERNDIM IQCS Neurotransmitters in CSF

Product name Control Neurotransmitters in CSF

Product code	Product code	Colour cap
	NEU-01.1	Green
	NEU-01.2	Red

Date of issue 24 May 2022

Batch numbers and production date	Batch number	Production date	Storage temperature
	 2021.1771	 2021-12	+2°C to + 8°C
	 2021.1772	 2021-12	

Reconstitution volume 0.25 mL

Estimated concentrations *	Analyte	Estimated concentrations (nmol/L)	
		Level 1	Level 2
	HVA (homovanillic acid)	98	609
5-HIAA	56	339	
3-MD (3-methyl dopa)	23	597	
5-HTTP (5-hydroxytryptophan)	18	365	

* See ERNDIM Internal Quality Control System at the reverse

Neurotransmitters in CSF ERNDIM IQCS

Intended purpose

These materials are control material (thus no calibrators) for the internal control of analytical systems for the determination of neurotransmitters in CSF.

Contents

Lyophilized artificial CSF to which neurotransmitter metabolites have been added to achieve an analytically and physiologically relevant level of the neurotransmitters in CSF.

Storage and stability

The product in lyophilized form is stable for at least 1 year when stored at +2°C to + 8°C. The date of production can be 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 0.25 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

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.

References

www.ERNDIMQA.nl

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