Product certificate ERNDIM IQCS Pterins in urine

Product name Control Pterins in urine

Product code

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

Date of issue 11 July 2024

Batch numbers and date of manufacture

Batch number	Date of manufacture
LOT 2024.1211	**2024-04**
LOT 2024.1212	**2024-04**

Storage temperature +2°C to +8°C

Reconstitution volume 1.0 mL

Estimated concentrations *

Analyte	**Estimated concentrations (µmol/L)**	
	Level 1	**Level 2**
Neopterin	16.0	127
Biopterin	11.5	61.7
Primapterin (7-Biopterin)	3.99	54.9
Isoxanthopterin	41.4	502

* See ERNDIM Internal Quality Control System at the reverse

Consult Instructions For Use

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Pterins in urine ERNDIM IQCS

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

Contents
Lyophilized human urine to which pterins have been added to achieve an analytically and physiologically relevant level of the pterins.

Storage and stability
The product in lyophilized form is likely stable for 2 years when stored at +2°C to + 8°C. Date of manufacture is 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. Let stand for 15 minutes at room temperature (do not expose to sunlight)
g. Process product as patient sample.
h. 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. 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

ERNDIM Internal Quality Control System Working Group