





Product certificate ERNDIM IQCS Purines & Pyrimidines

Product name Control Purines & Pyrimidines

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

Date of issue 04-02-2019

Batch numbers and Expiry date	Batch number	Exp. date stored at +2°C to +8°C
	 2018.3151	 2023-07
	 2018.3152	 2023-07

Reconstitution volume 5.0 mL

Estimated concentrations *

Analyte	Estimated concentrations (µmol/L)	
	Level 1	Level 2
2-Deoxyadenosine	16	42
2-Deoxyguanosine	10	27
2-Deoxyinosine	13	37
2-Deoxyuridine	14	38
5-OH-methyluracil	11	40
Adenine	14	57
Adenosine	13	54
AICAR	12	27
Creatinine	3000	5000
Dihydrothymine	32	94
Dihydrouracil	26	200
Guanosine	8	31
Hypoxantine	40	156
Inosine	12	52
Orotic Acid	14	128
Orotidine	1	1
Pseudo-uridine	45	84
Thymidine	13	27
Thymine	14	79
Uracil	27	112
Uric Acid	290	290
Xanthine	14	127

* See ERNDIM Internal Quality Control System at the reverse

Orotidine is spiked but not recovered

Uric Acid is high in the basic urine and thus not spiked and the same in both levels.

Purines & Pyrimidines ERNDIM IQCS

Intended purpose

These materials are control material (thus no calibrators) for the internal control of analytical systems for the determination of purines and pyrimidines in urine.

Contents

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

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 5 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.
2. Tested and found negative for Hepatitis B Surface Antigen (HbsAg), antibody to hepatitis C (HCV) and antibody to HIV.
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 C.W. Weykamp on behalf of the ERNDIM Internal Quality Control System Working Group

