





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 21-12-2018

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

The website for data management is an extension of the website for the ERNDIM schemes and can be used to manage the laboratories internal quality control data (not obligatory; this is an option to serve ERNDIM users). Results are entered and a report can be requested showing the results of all analytes in the last run in comparison with

- a) the running mean of the lab,
- b) the running mean of all labs using the batch of internal control material and
- c) the acceptance limits set by the lab.

With a simple click on a specific analyte a classic Shewhart Chart appears showing the cumulative data of the lab. Details can be found under www.erndimqa.nl (see also remark 1).

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