





## Product certificate ERNDIM IQCS Purines & Pyrimidines

**Product name** Control Purines & Pyrimidines

<b>Product code</b>	Product code	Colour cap
	PUR-02.1	Green
	PUR-02.2	Red

**Date of issue** 11 May 2022

<b>Batch numbers and Expiry date</b>	Batch number	Exp. date stored at +2°C to +8°C
	 2022.1371	 <b>2027-04</b>
	 2022.1372	 <b>2027-04</b>

**Reconstitution volume** 2.5 mL

**Estimated concentrations \***

Analyte	Estimated concentrations (µmol/L)	
	Level 1	Level 2
2-Deoxyadenosine	11	39
2-Deoxyguanosine	11	27
2-Deoxyinosine	10	36
2-Deoxyuridine	11	37
5-OH-methyluracil	10	46
Adenine	9	49
Adenosine	10	50
AICAR	10	22
Creatinine	3400	5700
Dihydrothymine	34	94
Dihydrouracil	27	193
Guanosine	11	32
Hypoxanthine	36	152
Inosine	11	51
Orotic Acid	9	123
Orotidine	1	2
Pseudo-uridine	40	72
Thymidine	10	24
Thymine	10	84
Uracil	18	100
Uric Acid	469	465
Xanthine	16	129

\* See ERNDIM Internal Quality Control System at the reverse

## Purines & Pyrimidines ERNDIM IQCS

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### 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.
- b. Insert a hollow needle through the stopper to remove the vacuum (to prevent material getting on the stopper)
- c. Remove stopper.
- d. Add 2.5 mL aqua destillata
- e. Replace stopper
- f. Let stand for 15 minutes at room temperature
- g. Mix carefully during 20 minutes at room temperature
- h. 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. 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

