



Productcertificate Special Assays in Urine

Productname Control Special Assays in Urine

Productcode

Productcode	Colour cap
SAU-01	Red

Batchnumbers and Expiry date

Batchnumber	Exp.date stored at +2°C to +8°C
LOT 2004.023	2012-06*

*On basis of ongoing stability-tests the Expiration date has been expanded to June 2012 (former Exp.date: 2010-06).

Reconstitution volume

5.0 mL

Calculated Consensus Values

Analyte	Calculated Consensus Value ($\mu\text{mol/L}$)	95% Confidence Interval
5-OH-Indolacetic acid ($\mu\text{mol/L}$)	56	51 – 60
Carnitine Free ($\mu\text{mol/L}$)	246	238 – 254
Creatine ($\mu\text{mol/L}$)	313	276 – 350
Creatinine (mmol/L)	8.0	7 – 9
Guanidinoacetate ($\mu\text{mol/L}$)	97	91 – 103
Homovanillic acid (HVA) ($\mu\text{mol/L}$)	54	51 – 58
Hydroxyproline ($\mu\text{mol/L}$)	507	483 – 531
Lactic acid (mmol/L)	5.1	4 – 6
Mucopolysaccharides (mg/L)	47	45 – 49
Orotic acid ($\mu\text{mol/L}$)	46	45 – 48
Pipecolic acid ($\mu\text{mol/L}$)	25	22 – 28
Sialic acid ($\mu\text{mol/L}$)	200	180 – 220
Sodium Thiosulfate ($\mu\text{mol/L}$)	11	0 – 28
Succinylacetone ($\mu\text{mol/L}$)	12	9 – 15
Uric acid ($\mu\text{mol/L}$)	320	304 – 336



Consult
Instructions
For Use



Special Assays in Urine

Intended purpose

Control of analytical systems for the determination of a variety of analytes in urine, relevant for inborn errors of metabolism.

Contents

Lyophilized human serum to which the respective analytes of interest have been added to achieve an analytically and physiologically relevant level.

Value Assignment

The specimens are prepared from equal amounts of the specimen pools used to manufacture the ERNDIM External Quality Assessment Scheme samples. The assigned values represent the average of the mean consensus concentrations of the 4 pools equal to the concentrations in the annual report (see reverse of this productcertificate).

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 productcertificate (reverse). The stability of the reconstituted product is 48 hours when handled appropriately: pure water, replacement of stopper and storage at 2-8 °C.

Instructions for use

- a. Remove cap and stopper. Open the vial carefully avoiding any loss of material.
- b. Add 5 mL aqua destillata (at room temperature)
- c. Replace stopper
- d. Let stand for 15 minutes at roomtemperature
- e. Mix carefully
- f. Analyse as patient sample

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

11 September 2007
Dr. C.W. Weykamp