

Product certificate Special Assays in Urine





Product name Control Special Assays in Urine

Product code

Level	Product code	Colour cap
1	SAU-01.1	Green
2	SAU-01.2	Red

Date of issue 12-12-2016

Batch numbers and Expiry date

Level	Batch number	Exp. date stored at +2°C to +8°C
1	 2016.0091	 2020-09
2	 2016.0092	 2020-09

Reconstitution volume

5.0 mL

Calculated Consensus Values

Analyte	Unit	Level 1		Level 2	
		Calculated Consensus Value *	Range Laboratories *	Calculated Consensus Value *	Range Laboratories *
5-OH-Indolacetic acid	µmol/L	82.6	68.2 - 97.0	23.3	17.7 - 28.8
Carnitine Free	µmol/L	73.0	57.8 - 88.3	391	319 - 463
Creatine	µmol/L	5703	4959 - 6447	499	393 - 604
Creatinine	mmol/L	3.99	3.5 - 4.4	7.26	6.6 - 7.9
Galactitol	µmol/L	240	189 - 291	83.4	64.7 - 102
Glycolic acid	µmol/L	61.1	40.2 - 82.0	190	130 - 250
Guanidinoacetate	µmol/L	120	101 - 140	743	643 - 844
Homovanillic acid (HVA)	µmol/L	80.6	69.8 - 91.4	22.6	18.2 - 26.9
Lactic acid	mmol/L	1.51	1.2 - 1.8	7.26	6.5 - 8.0
Mucopolysaccharides	mg/L	112	89.4 - 135	32.4	24.7 - 40.0
Orotic acid	µmol/L	18.6	14.3 - 22.8	87.0	72.6 - 101
Oxalic acid	µmol/L	290	191 - 388	39.8	20.7 - 59.0
Pipecolic acid	µmol/L	11.2	8.3 - 14.0	34.3	26.2 - 42.3
Sialic acid	µmol/L	272	205 - 338	84.6	59.6 - 110
Succinylacetone	µmol/L	11.0	5.9 - 16.1	31.8	20.7 - 42.8
Sulfocysteine	µmol/L	27.7	19.9 - 35.4	8.41	3.7 - 13.2

* See Value Assignment and Ranges at the reverse



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

Value Assignment and Ranges

Each level is prepared from equal amounts of two specimen pools which are used to manufacture the ERNDIM External Quality Assessment Scheme samples. The assigned values represent the average of the mean consensus concentrations of the 2 pools (see reverse of this product certificate). The range is based on the interlab variation of the 90% best performing laboratories in the EQA programme.

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 48 hours when handled appropriately: pure water, replacement of stopper and storage at 2-8°C.

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

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

Dr. C.W. Weykamp

