

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 05-12-2017

Batch numbers and Expiry date

Level	Batch number	Exp. date stored at +2°C to +8°C
1	LOT 2017.0091	2021-08
2	LOT 2017.0092	2021-08

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	19.9	14 - 26	72.5	59 - 86
Carnitine Free	µmol/L	383	322 - 444	81.1	63 - 99
Creatine	µmol/L	485	363 - 607	5774	4912 - 6635
Creatinine	mmol/L	7.30	6.5 - 8.1	4.01	3.6 - 4.5
Galactitol	µmol/L	86.8	68 - 106	246	199 - 292
Glycolic acid	µmol/L	197	147 - 246	70.2	49 - 91
Guanidinoacetate	µmol/L	116	97 - 136	749	648 - 849
Homovanillic acid (HVA)	µmol/L	80.7	69 - 92	22.9	20 - 26
Lactic acid	mmol/L	7.24	6.2 - 8.3	1.51	1.2 - 1.8
L-Cystine	µmol/L	158	128 - 189	298	259 - 338
Mucopolysaccharides	mg/L	30.5	24 - 37	107.9	89 - 127
Orotic acid	µmol/L	89.0	75 - 103	19.3	15 - 24
Oxalic acid	µmol/L	37.1	17 - 57	192	102 - 282
Pipecolic acid	µmol/L	35.5	28 - 43	11.4	9.0 - 14
Sialic acid	µmol/L	85.1	44 - 126	154	119 - 190
Succinylacetone	µmol/L	30.7	14 - 48	11.0	4.9 - 17
Sulfocysteine	µmol/L	8.89	4.4 - 13	29.2	21 - 38

* 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

