



Product certificate Special Assays in Urine

Product name Control Special Assays in Urine

Product code	Product code	Colour cap
	SAU-01	Red

Batch numbers and Expiry date	Batch number	Exp. date stored at +2°C to +8°C
	LOT 2010.171	2015-04

Reconstitution volume 5.0 mL

Calculated Consensus Values

Analyte	Unit	Calculated Consensus Value *	95% Confidence Interval *	Expected Range results in Laboratory *
5-OH-Indolacetic acid	µmol/L	54.2	50 - 59	31 - 78
Carnitine Free	µmol/L	247	238 - 256	174 - 320
Creatine	µmol/L	326	298 - 354	145 - 507
Creatinine	mmol/L	8.0	7.9 - 8.1	6.9 - 9.1
Guanidinoacetate	µmol/L	117	111 - 123	79 - 155
Homovanillic acid (HVA)	µmol/L	52.1	48 - 56	25 - 79
Hydroxyproline	µmol/L	507	485 - 529	387 - 627
Lactic acid	mmol/L	5.25	5.0 - 5.5	3.3 - 7.2
Mucopolysaccharides	mg/L	54.4	52 - 57	35 - 74
Orotic acid	µmol/L	47	45 - 49	31 - 63
Pipecolic acid	µmol/L	25.9	23 - 29	12 - 40
Sialic acid	µmol/L	180.0	155 - 205	66 - 294
Succinylacetone	µmol/L	13.8	11 - 17	3 - 25
Uric acid	µmol/L	686	661 - 711	505 - 867

* See Value Assignment and Ranges at the reverse



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 and Ranges

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 product certificate). The column with the 95% Confidence Interval shows the confidence interval of the assigned value (narrow range). The column with the expected range shows the range in which results of individual laboratories can be expected (wide range).

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

November 2011
Dr. C.W. Weykamp