


Product certificate Organic Acids

Product name Control Organic Acids

Product code	Product code	Colour cap
	ORG-01	Blue

Date of issue 13-12-2016

Batch numbers and Expiry date	Batch number	Exp. date stored at +2°C to +8°C
	LOT 2016.007	 2020-09

Reconstitution volume 10.0 mL

Calculated Consensus Values	Analyte	Calculated Consensus Value (µmol/L) *	95% Confidence Interval *	Expected Range results in Laboratory *
	2-Methylcitric acid	4.58	3 - 6	0 - 11
	2-OH Glutaric acid	151	140 - 162	104 - 198
	3 Methylglutaconic acid	31.2	28 - 34	19 - 44
	3 Methylglutaric acid	39.9	38 - 42	31 - 49
	3-OH-3-methylglutaric acid	80.0	68 - 92	31 - 129
	3-OH-Glutaric acid	4.03	2 - 6	0 - 11
	3-OH-Isovaleric acid	42.4	37 - 47	20 - 64
	4-OH-Butyric acid	65.8	57 - 75	30 - 102
	Adipic Acid	78.6	74 - 83	57 - 100
	Creatinine	3220	3174 - 3266	3019 - 3421
	D,L-Glyceric acid	123	109 - 137	67 - 179
	Ethylmalonic acid	37.3	35 - 40	26 - 48
	Fumaric acid	60.8	56 - 65	40 - 81
	Glutaric acid	109.0	103 - 115	80 - 138
	Glycolic acid	237	222 - 252	174 - 300
	Hexanoylglycine	18.6	17 - 20	12 - 25
	Keto-glutaric acid	197	170 - 224	82 - 312
	Methylmalonic acid	155	147 - 163	114 - 196
	Mevalonic acid	63.2	51 - 75	19 - 108
	N-acetylaspartic acid	57.5	49 - 66	20 - 95
	Pyroglutamic acid	326	290 - 362	172 - 480
	Sebacid Acid	55.8	51 - 60	35 - 77
	Suberic acid	76.9	71 - 83	50 - 104
	Tiglylglycine	87.8	77 - 99	45 - 131
	Vanillactic acid	23.0	20 - 26	14 - 32

* See Value Assignment and Ranges at the reverse

Organic Acids

Intended purpose

These materials are control materials (thus no calibrators) for the control of analytical systems for the determination of organic acids in urine.

Contents

Lyophilized human urine to which organic acids have been added to achieve an analytically and physiologically relevant level of the organic acids.

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 70% 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 10 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