


Product certificate Organic Acids

Product name Control Organic Acids

Product code	Product code	Colour cap
	ORG-01	Blue

Batch numbers and Expiry date	Batch number		Exp. date stored at +2°C to +8°C	
	LOT	2010.007		2014-09

Reconstitution volume 10.0 mL

Calculated Consensus Values

Analyte	Calculated Consensus Value (µmol/L) *	95% Confidence Interval *	Expected Range results in Laboratory *
Hexanoylglycine	32.2	28 - 36	16 - 48
3 Methylglutaraat	69.5	66 - 73	57 - 82
Glutaraat	101	95 - 107	76 - 126
Fumaric acid	62.7	57 - 68	41 - 85
D,L-Glyceric acid	461	391 - 531	200 - 722
Suberate	216	198 - 234	138 - 294
3-OH-Butyrate	1192	984 - 1400	328 - 2056
Pyroglutamic acid	2414	1832 - 2996	256 - 4572
Adipic Acid	217	200 - 234	149 - 285
Sebacid Acid	214	189 - 239	111 - 317
N-Acetyl Aspartic acid	3266	2647 - 3885	908 - 5624
Methylmalonate	1473	1343 - 1603	862 - 2084
Ethylmalonate	98.8	93 - 104	75 - 123
Keto-glutaric acid	395	350 - 440	214 - 576
4-OH-Butyric acid	86.9	66 - 107	9 - 165
Tiglylglycine	89.1	79 - 100	51 - 127
3-OH-Isovaleraat	184	162 - 206	95 - 273
Glycolate	194	175 - 213	119 - 269
D-a-OH-Glutarate	187	173 - 201	127 - 247
Mevalonic acid	293	225 - 361	59 - 527

* See Value Assignment and Ranges at the reverse



Consult
Instructions
For Use



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

November 2011
Dr. C.W. Weykamp