



Product certificate Special Assays in Serum

Product name Control Special Assays in Serum

Product code	Product code	Colour cap
	SAS-01	Green

Batch numbers and Expiry date	Batch number	Exp. date stored at +2°C to +8°C
	LOT 2010.008	2014-09

Reconstitution volume 5.0 mL

Calculated Consensus Values

Analyte	Unit	Calculated Consensus Value *	95% Confidence Interval *	Expected Range results in Laboratory *
3-OH-Butyric acid	mmol/L	2.54	2 - 3	2 - 3
7-Dehydrocholesterol	µmol/L	129	121 - 137	73 - 185
C22:0 Behenic Acid	µmol/L	88.6	86 - 91	68 - 109
C24:0 Lignoceric acid	µmol/L	78.1	76 - 80	58 - 98
C26:0 Cerotic acid	µmol/L	4.74	5 - 5	3 - 7
Carnitine Free	µmol/L	89.8	88 - 92	69 - 110
Cholestanol	µmol/L	54.9	49 - 61	29 - 81
Creatine	µmol/L	66.9	65 - 69	52 - 81
Galactose	µmol/L	933	830 - 1036	623 - 1243
Guanidino acetic acid	µmol/L	11.8	11 - 12	9 - 15
Homocysteine	µmol/L	66.5	65 - 68	52 - 81
Lactic acid	mmol/L	6.1	6 - 6	5 - 7
Methylmalonic acid	µmol/L	526	497 - 555	303 - 749
NEFA	µmol/L	558	536 - 580	413 - 703
Phytanic acid	µmol/L	20	19 - 21	12 - 28
Pipecolic acid	µmol/L	23.8	23 - 25	17 - 31
Pristanic acid	µmol/L	5.87	5 - 6	3 - 9
Pyruvic acid	mmol/L	0.312	0.299 - 0.325	0.185 - 0.439

* See Value Assignment and Ranges at the reverse



Consult Instructions For Use



Special Assays in Serum

Intended purpose

Control of analytical systems for the determination of a variety of analytes in serum. 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 5.0 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. Tested and found negative for Hepatitis B Surface Antigen (HbsAg). antibody to hepatitis C (HCV) and antibody to HIV.
3. 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