



Product certificate Special Assays in Serum

Product name Control Special Assays in Serum

Level	Product code	Colour cap
1	SAS-02.1	Green
2	SAS-02.2	Red

Date of issue 05-12-2017

Level	Batch number	Exp. date stored at +2°C to +8°C
1	LOT 2017.0081	 2021-09
2	LOT 2017.0082	 2021-09

Reconstitution volume 5.0 mL

Calculated Consensus Values

Analyte	Unit	Level 1		Level 2	
		Calculated Consensus Value *	Range Laboratories *	Calculated Consensus Value *	Range Laboratories *
3 OH Butyric acid	mmol/L	0.498	0.41 - 0.58	2.91	2.5 - 3.3
7-Dehydrocholesterol	µmol/L	54.5	38 - 71	33.2	22 - 44
7-Ketocholesterol	µmol/L	0.865	0.50 - 1.2	0.86	0.43 - 1.3
C22:0 Behenic acid	µmol/L	69.0	58 - 80	100	85 - 116
C24:0 Lignoceric acid	µmol/L	63.0	52 - 74	70.1	57 - 83
C26:0 Cerotic acid	µmol/L	4.09	3.1 - 5.1	2.70	2.2 - 3.2
Carnitine Free	µmol/L	40.4	32 - 49	103	83 - 124
Cholestane-3b, 5a, 6b-triol	µmol/L	0.286	0.14 - 0.43	0.530	0.37 - 0.69
Cholesterol	µmol/L	46.9	39 - 55	41.9	33 - 50
Cholesterol	mmol/L	4.66	4.1 - 5.3	4.62	4.1 - 5.1
Creatine	µmol/L	43.5	37 - 50	77.4	67 - 88
Galactose	µmol/L	815	670 - 959	725	571 - 878
Guanidino acetic acid	µmol/L	11.1	9.2 - 13	10.6	8.7 - 13
Homocysteine	µmol/L	25.7	18 - 33	85.1	56 - 114
Lactic acid	mmol/L	4.48	4.1 - 4.9	6.55	6.0 - 7.1
Lyso Gb3	nmol/L	5.07	2.9 - 7.3	71.3	43 - 100
Methylmalonic acid	µmol/L	10.0	8.4 - 12	233	201 - 264
NEFA	µmol/L	653	562 - 743	656	578 - 735
Phytanic acid	µmol/L	8.30	6.4 - 10	14.4	11 - 18
Pipicolinic acid	µmol/L	20.1	16 - 24	15.0	12 - 18
Pristanic acid	µmol/L	1.35	1.0 - 1.7	5.85	4.6 - 7.1
Pyruvic acid	mmol/L	0.210	0.16 - 0.26	0.355	0.26 - 0.45

* See Value Assignment and Ranges at the reverse

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

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 5.0 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

Dr. C.W. Weykamp