Product certificate ERNDIM IQCS Special Assays in Serum

Product name Control Special Assays in Serum

Product code

Product code	Colour cap
SAS-02.1	Green
SAS-02.2	Red

Date of issue 7 February 2023

Batch numbers and Expiry date

Batch number	Exp. date stored at +2°C to +8°C
LOT 2022.1851	**2027-07**
LOT 2022.1852	**2027-07**

Reconstitution volume 5.0 mL

Estimated concentrations *

Analyte	Unit	Estimated concentrations	
		Level 1	Level 2
3-OH Butyric acid	mmol/L	690	1980
7-Dehydrocholesterol	µmol/L	15.9	89.1
7-Ketocholesterol	µmol/L	0.45	1.82
C22:0 Behenic acid	µmol/L	63.0	96.0
C24:0 Lignoreceric acid	µmol/L	51.0	89.0
C26:0 Cerotic acid	µmol/L	1.07	5.77
Carnitine free	µmol/L	29.6	51.6
Cholestane-3b, 5a, 6b-triol	µmol/L	0.09	0.28
Cholestanol	µmol/L	17.9	46.5
Creatine	µmol/L	61.2	91.1
Galactose	µmol/L	132	1302
Guanidone acetic acid	µmol/L	4.68	9.8
Homocysteine	µmol/L	16.5	60.0
Lactic acid	mmol/L	2.79	7.26
Lyso Gb3	nmol/L	20.7	48.4
Methylmalonic acid	µmol/L	10.3	58.4
Phytanic acid	µmol/L	6.6	21.8
Pipecolic acid	µmol/L	11.2	34.8
Pristanic acid	µmol/L	1.34	5.16
Pyruvic acid	mmol/L	0.050	0.206

* See ERNDIM Internal Quality Control System at the reverse

Consult Instructions For Use

MCA Laboratory – Streekziekenhuis Koningin Beatrix – Beatrixpark 1 – 7101 BN Winterswijk – The Netherlands
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Special Assays in Serum ERNDIM IQCS

Intended purpose
These materials are control material (thus no calibrators) for the internal 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 the respective analytes.

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 comparable to patient samples.

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

ERNDIM Internal Quality Control System: the Concept
The ERNDIM Internal Quality Control System (IQCS) consists of samples and a website for data management.

Samples
Samples contain analytes specifically selected for laboratories active in the field of inborn errors of metabolism. They come in two levels (1=low and 2=high) with for each analyte a relevant concentration.

Data Management
ERNDIM offers users of control materials a data management system (Note: this is an option to serve users; users do not have the obligation to use it). The strength of this system is that it does not only monitor the data of the laboratory but also compares the labs results with results of labs using the same batch of internal control materials.
In essence users can submit results every time they do an analytical run with the control material and then download two reports.
The Review Day Report shows the results of the last run in comparison to
a) the acceptance limits set by the lab,
b) the mean of all previous runs of the lab
c) the mean of all laboratories.
By clicking on the name of a specific analyte in the report, Shewhart charts of that analyte are shown.
The Cumulative Table report shows the cumulative data of the lab.

Details can be found under www.erndimqa.nl/General information/Use Website.

Remark
On delivery of the control materials, the certificate in the package insert shows the values as measured by a peer laboratory. Once in use laboratories submit their results and the reports will show the trimmed mean of all laboratories. This mean is a running mean which changes with every new submission: Thus a dynamic assigned value resulting from “crowd targeting”.

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), antibody to HIV and HIV antigen.
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 E.A.E. van der Hagen on behalf of the ERNDIM Internal Quality Control System Working Group