





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 4 October 2021

Batch numbers and Expiry date	Batch number	Exp. date stored at +2°C to +8°C
	 2020.1321	 2025-05
	 2020.1322	 2025-05

Reconstitution volume 5.0 mL

Estimated concentrations *

Analyte	Estimated concentrations (µmol/L)		
	Unit	Level 1	Level 2
3-OH-Butyric acid	mmol/L	0.84	1.8
7-DHC	µmol/L	16	80
7-Ketocholesterol	µmol/L	0.551	1.63
C22:0 Behenic acid	µmol/L	48	79
C24:0 Lignoceric acid	µmol/L	42	78
C26:0 Cerotic acid	µmol/L	0.86	4.6
Carnitine free	µmol/L	41.7	69
Cholestane 3b,5a,6b triol	µmol/L	0.129	0.404
Cholestanol	µmol/L	21	66
Creatine	µmol/L	61	93
GAA	µmol/L	3.1	8.7
Galactose	µmol/L	82	1037
Homocysteine	µmol/L	14.2	53
Lactic acid	mmol/L	2.7	7.4
Lyso Gb3	µmol/L	0.033	0.060
Methylmalonic acid	µmol/L	10.4	53
Phytanic acid	µmol/L	2.7	13.1
Pipecolic acid	µmol/L	9.8	28.4
Pristanic acid	µmol/L	1.1	4.5
Pyruvic acid	µmol/L	n.d.	n.d.

n.d., not determined

* See ERNDIM Internal Quality Control System at the reverse

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](http://www.erndimqa.nl/General%20information/Use%20Website).

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

