





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 11-10-2018

Batch numbers and Expiry date	Batch number	Exp. date stored at +2°C to +8°C
	 2018.2161	 2023-07
	 2018.2162	 2023-07

Reconstitution volume 5.0 mL

Estimated concentrations *

Analyte	Estimated concentrations		
	Unit	Level 1	Level 2
3-OH-Butyric acid	mmol/L	0.7	1.9
7-DHC	µmol/L	20	48
7-Ketocholesterol	µmol/L	0.5	1.8
C22:0 Behenic acid	µmol/L	55	99
C24:0 Lignoceric acid	µmol/L	45	77
C26:0 Cerotic acid	µmol/L	0.8	4.8
Carnitine free	µmol/L	42	71
Cholestane 3b,5a,6b triol	µmol/L	0.13	0.39
Cholesterol	µmol/L	20	64
Creatine	µmol/L	58	90
GAA	µmol/L	4.8	14.2
Galactose	µmol/L	150	1180
Homocysteine	µmol/L	19	77
Lactic acid	µmol/L	2.7	6.6
Lyso Gb3	µmol/L	0.02	0.04
Methylmalonic acid	µmol/L	10	57
Phytanic acid	µmol/L	5.8	13.1
Pipecolic acid	µmol/L	11	31
Pristanic acid	µmol/L	1.3	3.5

* 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

The website for data management is an extension of the website for the ERNDIM schemes and can be used to manage the laboratories internal quality control data (not obligatory; this is an option to serve ERNDIM users). Results are entered and a report can be requested showing the results of all analytes in the last run in comparison with

- a) the running mean of the lab,
- b) the running mean of all labs using the batch of internal control material and
- c) the acceptance limits set by the lab.

With a simple click on a specific analyte a classic Shewhart Chart appears showing the cumulative data of the lab. Details can be found under www.erndimqa.nl (see also remark 1).

Remarks

1. The ERNDIM IQCS will be implemented in steps between July 2018 and January 2020. The release of samples for amino acids and organic acids (July 2018) and special assays in serum (October 2018) will be a couple of months ahead of the availability of the website (estimated end of 2018). Once the website is released all users will be informed that they can start using it.
2. 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) 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 on behalf of the ERNDIM Internal Quality Control System Working Group

