

To the participants of ERNDIM schemes and users of control materials

Winterswijk, 1 July 2018

Dear colleague,

Until now ERNDIM control materials are related to ERNDIM EQA samples. This approach has several disadvantages:

- a. Internal and external quality control samples are not independent
- b. Levels are not always different enough
- c. Analytes change from batch to batch
- d. Concentrations change from batch to batch
- e. Delay time between manufacture and release due to the value assignment procedure
- f. For some groups only one concentration level is available

During the meeting of the board of scientific advisors in Lyon on 16th February 2017 a working group was formed to make a plan for to reorganize the ERNDIM internal control system. The plan "ERNDIM Internal Quality Control System" (ERNDIM IQCS) was presented and approved during the board meeting of 28 November 2017 in Manchester.

ERNDIM IQCS: samples

In the new approach EQA and control samples are not related anymore. Other characteristics are:

- a. There are two concentration levels for each group of analytes
- b. The most suitable low and high concentration levels are defined by the respective scientific advisors
- c. Analytes and their concentrations will be approximately the same in consecutive batches of control material
- d. There is a short delay time between manufacture and release of the control materials
- e. ERNDIM EQA and internal control sample are independent

ERNDIM IQCS: data management

On the website a new section for data management completes the ERNDIM internal Quality Control System. Laboratories have the option to submit results and request reports showing their result in the last run in comparison to defined acceptance limits, their own historical data and the mean of all laboratories using the same batch control material.

Assigned values: crowd targeting

On delivery of the control material the certificate in the package insert shows the values measured by 1 or 2 peer laboratories. Once in use laboratories submit their results and the reports deal with the trimmed mean of all laboratories. This mean is a running mean which changes with every new submission. Thus, the assigned value is the result of "crowd targeting"

Transition period

The new system will gradually replace the old system between July 2018 and January 2020. The table shows the (estimated) transition dates. The website is estimated to be ready for use in October 2018. The implication is that the new control material for amino acids and organic acids will be available before the website can be operated. Once the website is released all users will be informed by mail.

Estimated transition dates and packages

<i>Control material</i>	<i>Classic Control material</i>		<i>New Control material</i>	
	<i>Available till</i>	<i>Package</i>	<i>Available from (estimated)</i>	<i>Package</i>
Amino Acids	June 2018	6 vials Level 1 and 6 vials Level 2	July 2018	6 vials Level 1 and 6 vials Level 2
Organic Acids	May 2018	6 vials (1 level only)	July 2018	6 vials Level 1 and 6 vials Level 2
Special Assays Serum	September 2018	6 vials Level 1 and 6 vials Level 2	October 2018	6 vials Level 1 and 6 vials Level 2
Special Assays Urine	December 2018	6 vials Level 1 and 6 vials Level 2	January 2019	6 vials Level 1 and 6 vials Level 2
Acylcarnitines	September 2019	12 vials (1 level only)	October 2019	6 vials Level 1 and 6 vials Level 2
Purines and Pyrimidines	December 2019	6 vials (1 level only)	January 2020	6 vials Level 1 and 6 vials Level 2

Information and online ordering: www.erndimqa.nl: General Information – Control Materials

Certificates

Certificates are, as usual, in print in the package insert on delivery and on the website. On the website the replacement of certificates of old and new control material will parallel the replacement of the materials itself.

Questions

In case of questions please contact website manager Irene de Graaf (i.deGraaf@skbwinterswijk.nl)

We hope (and expect) that the new ERNDIM Internal Control System will better serve the users.

Best regards,

The Working Group ERNDIM Internal Control System

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