

Product certificate Oligosaccharide kit







Product name Educational Oligosaccharide Kit

Product code

Product code	Colour cap
OLI-01	Blue

Date of issue 05-12-2019

Batch numbers and Expiry date

Batch number	Samples	Stored at -24°C to -16°C
 2016.418	Oligo-3	 2026-08
 2013.174	Oligo-7	 2023-03
 2018.237	Oligo-1, 2, 4, 5, 8 and 9	 2028-04

Reconstitution volume

0.3 mL

Description of the samples

Sample ID	Type	Creatinine mmol/L	Age
Oligo-1	GM1 gangliosidosis	1.6	1 year
Oligo-2	GM2 gangliosidosis	3.8	1.3 year
Oligo-3	Pompe disease (infantile)*	6.5	12 year
Oligo-4	Aspartylglucosaminuria	10.4	8.5 year
Oligo-5	α -mannosidosis	4.6	18 year
Oligo-7	Sialidosis	4.7	Adult
Oligo-8	Fucosidosis	3.0	7 year
Oligo-9	β -mannosidosis	7.9	9 year

* Patient under treatment (ERT), but tetrasaccharide grossly elevated

Educational Oligosaccharide Kit

Intended purpose

The ERNDIM Educational Oligosaccharide Kit contains disease-positive samples of Oligosaccharidoses. These samples may serve as positive controls in quality assessment of analytical systems intended for screening of oligosaccharidoses.

Contents

Lyophilized human urine.

Value Assignment and Ranges

Sample ID and diagnosis are listed in the table on the front page. Creatinine and age have been included to facilitate selection of sample volume to be used in the analysis.

From the oligosaccharidoses currently known some are not included in the kit due to limited sample availability. When new oligosaccharidosis samples become available, the kit may be upgraded.

Storage and stability

The product in lyophilized form is stable for 10 years when stored at -24°C to -16°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. The reconstituted product may be stored frozen for future use; in this case treat as a regular urine samples according to local procedures.

Instructions for use

- a. Remove cap and stopper.
- b. Add 0.3 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. 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 Outdated and left-over material should be discarded as potentially infectious material, according to the procedures in your institute.
3. The ERNDIM Educational Oligosaccharide Kit is not intended to establish diagnosis by means of comparison of the patterns of diagnostic samples to the Oligosaccharide Kit samples. Analysis of oligosaccharides in urine is a screening method. When an oligosaccharidosis is suspected on the basis of screening results, diagnosis must be established by enzyme test.

Remarks

1. Protocol for analysis can be requested from www.ERNDIM.org.
2. Technical questions about the kit can be asked via email to mca.office@skbwinterswijk.nl.
3. Other questions can be asked via email to George Ruijter (g.ruijter@erasmusmc.nl) or Petr Chrastina (petr.charstina@lf1.cuni.cz).

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