UniLab N

DiaSystem Scandinavia AB

Control serum for use as control of accuracy and precision of tests for quantitative in vitro determination of various analytes on photometric systems

ORDER INFORMATION

07 00123 70 04 0030	6 x 5 mL
07 00123 70 04 0100	20 x 5mL

DESCRIPTION

UniLab N is a lyophilized control based on human blood material (serum) and contains drugs, organic and non-organic chemicals and biological material of specified origin. The concentrations are either at normal or at borderline pathological levels.

Analyte	Origin
Alkaline Phosphatase	Calf (intestine)
Alanine Aminotransferase	Porcine (heart)
Aspartate Aminotransferase	Porcine (heart)
α-Amylase	Porcine (pancreas)
Bilirubin	Porcine/Bovine
Creatine kinase	Human, recombinant
Glutamate dehydrogenase	Bovine (liver)
γ-Glutamyltransferase	Porcine (kidney)
Lactate dehydrogenase	Porcine (heart)
Lipase	Human, recombinant

The concentration of the biological material does not exceed the maximum, lot specific target value concentration of the analyte.

CONTROL STABILITY AND STORAGE

Vials of UniLab N must be stored at 2 - 8 °C.
Unopened: until the end of the indicated month of expiry.

Once reconstituted, UniLab N can be used within the period reported in the table below if stored tightly closed at the indicated temperature.

	+ 4 °C
Bilirubin (in the dark), ALAT, ASAT	2 days
Other analytes	7 days

	+ 25 °C
ALAT	2 hours
CK-NAC, CK-MB	4 hours
Other analytes	8 hours

	- 20 °C *
Bilirubin	14 days
Other analytes	30 days

* freeze only once!

WARNINGS AND PRECAUTIONS

1. Each individual blood donation used for production of UniLab N was found to be non-reactive when tested with approved methods for HBsAg, anti-HIV 1+2 and anti-HCV. As there is no possibility to exclude definitely that products derived from human blood transmit infectious agents, it is recommended to handle the control with the same precautions used for patient specimens.
2. UniLab N contains biological material of specified origin. The controls should be handled as potentially infectious and with the same precautions used for patient specimens
3. Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
4. For professional use only!

WASTE MANAGEMENT

Please refer to local legal requirements

CONTROL PREPARATION

The lyophilizate is vacuum sealed, therefore the vial should be opened very carefully to avoid loss of dried material. For reconstitution add exactly 5 mL of distilled water. Close the vial carefully and allow the control to stand for 30 minutes swirling occasionally. Avoid foaming! Do not shake!

PROCEDURE

Please refer to the reagent package insert for instructions for use.

ASSAY VALUES AND RANGES

The analyte concentrations contained in UniLab N are specific and only valid for the corresponding lot and thus stated in the value sheet of the lot involved. All assay values have been established within standardized conditions with the method stated in the value sheet by using the reagents specified via the product code.
Ranges of acceptance were calculated as assigned value ± the maximum tolerable deviation of a single value according to the Guidelines of the German Federal Medical Council (Rilibaek) from 2003 [3]. For analytes not listed in the Guidelines of the German Federal Medical Council (Rilibaek) ranges are indicated with a deviation of ±20% from the given mean value.
Each laboratory should establish corrective action in case of deviations in control recovery.

LITERATURE

1. Röhle G, Siekmann L. Quality assurance of quantitative determination. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1393-1401
2. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395).
3. Richtlinie der Bundesärztekammer zur Qualitätssicherung quantitativer laboratoriumsmedizinischer Untersuchungen. Deutsches Ärzteblatt 2003; 100:A 3335-38.

MANUFACTURER

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