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DIACON LIPIDS
(Lipid Control Serum Normal)

Assayed quality control material for monitoring analytical assay performance of quantitative in vitro determination of lipids.

REF	Content	
D99486	3 x 3 mL	Control Serum
D99486SV	1 x 3 mL	Control Serum

For professional in vitro diagnostic use only.

GENERAL INFORMATION

Shelf life 36 months
Storage 2 - 8 °C

INTENDED USE

Assayed quality control material for monitoring analytical assay performance of quantitative in vitro determination of lipids.

REAGENT COMPOSITION

Diacon Lipids is a lyophilized control based on human blood material (serum) with additives of purified material of human origin.

MATERIAL REQUIRED BUT NOT PROVIDED

- Clinical chemistry analyser.

REAGENT PREPARATION

1. Open the vial very carefully, avoiding any loss of the lyophilized material.
2. Add exactly 3 ml of distilled water (inaccurate reconstitution of the control can cause erroneous results).
3. Close the vial carefully and allow the control to stand for 30 min.
4. Dissolve contents completely by occasionally swirling gently, avoiding the formation of foam. Do not shake!
5. Transfer the quantity needed for determination into a clean sample vial and handle like a patient sample.

Frozen aliquots:
Leave frozen aliquots of the reconstituted control in the dark at room temperature (18 – 25 °C) until they are completely unfrozen. To homogenize, slightly swivel aliquots and immediately afterwards use them for determination.

STORAGE AND STABILITY

Storage:	at 2 – 8 °C		
Stability:	until indicated date of expiration		
Stability after reconstitution:			
	-20 °C	2 – 8 °C	15 – 25 °C
NEFA	not possible	7 days	8 hours
Other analytes	30 days	7 days	8 hours

Proper storage and handling of this product must be observed.
Avoid contamination! Freeze only once!

WARNINGS AND PRECAUTIONS

1. Only blood donations of European origin were used for the production of Diacon Lipids which were found to be non-reactive when tested with approved methods for HBsAg, anti-HIV 1+2 and anti-HCV. Moreover, HCV and HIV were additionally tested by PCR. As there is not 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. Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
3. For professional use only!

TEST PROCEDURE

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

LOT SPECIFIC CONTROL VALUES AND RANGES

The analyte concentrations contained in Diacon Lipids are specific and only valid for the corresponding lot. Please refer to the enclosed table. All values have been established within standardized conditions with the method stated in the value sheet using the corresponding Dialab reagents.
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 (Rilibäk) from 2003 [3]. For analytes not listed in the Guidelines of the German Federal Medical Council (Rilibäk) ranges are indicated with a deviation of ± 20% from the given mean.
Each laboratory should establish corrective action in case of deviations in control recovery.

LIMITATIONS

Compatibility of Diacon Lipids is only guaranteed if those methods stated in the enclosed table are used. When using Diacon Lipids with other methods, proceed with extreme caution. In such case, values found might vary considerably from those stated. All changes made in method standardization, in applications, reagent compositions or other influences may generate value deviations.

WASTE MANAGEMENT

Please refer to local legal requirements.

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 laboratoriums-medizinischer Untersuchungen. Deutsches Ärzteblatt Jg. 100, Heft 50; 12. Dezember 2003.

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