Lyophilized Serum Control

DIACON LIPIDS HIGH

(Assayed Lipid Control Serum Abnormal)

Lyophilized control serum for the control of accuracy and precision of quantitative in vitro determination of lipids on photometric systems.

REF	Cont.	
D11487	**3 x 3 ml**	Control Serum
D11487SV	**1 x 3 ml**	Control Serum
D11487VSV	**1 x 3 ml**	Control Serum

Additionally offered:

D96112B	1 x 1000 ml	Cholesterol Reagent
D95116	5 x 100 ml	Cholesterol Reagent
D00127	5 x 50 ml	HDL-Chol. precip. Reagent
D00129	5 x 10 ml	HDL-Chol. precip. Reagent
F03100	5 x 100 ml	Chol. HDL Direct Reagent
F03115	5 x 50 ml	Chol. HDL Direct Reagent
F05365	5 x 50 ml	Chol. LDL Direct Reagent
F05367	5 x 10 ml	Chol. LDL Direct Reagent
D07940	5 x 25 ml	NEFA Reagent
D07950	5 x 10 ml	NEFA Reagent
D98386B	1 x 1000 ml	Triglycerides Reagent
D00389	5 x 100 ml	Triglycerides Reagent
D96388	5 x 50 ml	Triglycerides Reagent

COMPOSITION

Lyophilized human-based serum
Additives of purified material of human origin

CONTROL PREPARATION

1. Open the vial very carefully, avoiding any loss of the lyophilized material.
2. Add exactly 3 ml of dist. 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.

CONTROL STABILITY AND STORAGE

Storage: at 2 – 8 °C
Stability: until the end of the indicated month of expiry.

Stability after reconstitution (tighlty closed):

	15 –25°C	2 – 8 °C	- 20°C
NEFA:	8 hours	7 days	not possible
Other analytes:	8 hours	7 days	30 days

CLOSE IMMEDIATELY AFTER USE! FREEZE ONLY ONCE!

Avoid bacterial contamination. Do not use the product if there is visible evidence of microbial growth in the vial.

Improper handling and/or storage of the control can affect results.

LOT SPECIFIC ASSAY VALUES AND RANGES

The analyte concentrations contained in Diacon Lipids High are specific and only valid for the corresponding lot. Please refer to the table below. 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 check if the reference range is transferable to its own conditions and regulatory requirements. Where appropriate, the values stated in this document are to be regarded as a guideline and own mean values and acceptance limits have to be determined.
Each laboratory should establish corrective action in case of deviations in control recovery. These deviations might be attributed to varying laboratory procedures, to instruments, reagents or modified test methods.

TEST PROCEDURE

Please refer to the reagent package insert for instructions for use. Each laboratory has to establish procedures for quality assurance which fulfil all national requirements.

LIMITATION

Compatiblity of Diacon Lipids High is only guaranteed if those methods stated in the table below are used. When using Diacon Lipids High 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.

WARNINGS AND PRECAUTIONS

Diacon Lipids High is intended for professional in vitro diagnostics.

1. Only blood donations of European origin which were found to be non-reactive when tested with approved methods for HBsAg, anti-HIV 1+2 and anti-HCV were used for the production of Diacon Lipids High. Moreover, HCV and HIV were additionally tested by PCR. 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. Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

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.

LOT SPECIFIC ASSAY DATA

LOT NUMBER	0871201

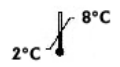
EXP.	2013/08

COMPONENTS	METHOD	CONVENTIONAL UNITS			UNIT CONV.	STANDARD INTERN. UNITS		
		MEAN	RANGE	UNITS	X FACTOR	MEAN	RANGE	UNITS
CHOL Cholesterol total	CHOD-PAP	249	214 - 284	mg/dl	0.026	6.44	5.54 – 7.34	mmol/L
F-CHOL* Free cholesterol	CHOD-PAP	59.1	47.3 – 70.9	mg/dl	0.026	1.53	1.22 – 1.83	mmol/L
CHOL-HDL	CHOD-PAP, precipitation	In eval.		mg/dl	0.026	In eval.		mmol/L
Cholesterol-HDL	Immunoinhibition	45.2	36.2 – 54.2	mg/dl	0.026	1.17	0.94 – 1.40	mmol/L
CHOL-LDL Cholesterol-LDL	Enzym. Select. Protection	125	100 – 150	mg/dl	0.026	3.23	2.59 – 3.88	mmol/L
NEFA Non-esterified fatty acids	ACOD-PAP	11.5	9.18 – 13.8	mg/dl	0.0354	0.41	0.32 – 0.49	mmol/L
PL* Phospholipids	enzymatic	296	237 – 355	mg/dl	0.0129	3.82	3.06 – 4.58	mmol/L
TG Triglycerides	GPO-PAP	277	222 - 332	mg/dl	0.0113	3.12	2.50 – 3.74	mmol/L

Assigned values and ranges, provided for listed components are derived using DIALAB reagents

Exception: assigned values and ranges market with an asterisk * are established for other brands.

The user should make sure that values are still valid.



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