


LDL-D CHOLESTEROL KIT
 (Direct Enzymatic Method)
 (For veterinary invitro diagnostic use only)

INTENDED USE

QUADRAPED™ LDL-D Cholesterol kit is used for the determination of LDL Cholesterol in serum/plasma.

SUMMARY

The LDL particles are lipoproteins that transport cholesterol to the cells. Often called "bad cholesterol" because high levels are risk factor for coronary heart disease and are associated with obesity, diabetes and nephrosis. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE

Direct determination of serum LDLc (low-density lipoprotein cholesterol) levels without the need for any pre-treatment or centrifugation steps. The assay takes place in two steps. First by the elimination of lipoprotein non - LDL Cholesterol and then the measurement of LDLc. The intensity of the colour formed is proportional to the LDLc concentration in the sample.

Elimination of non-LDL Cholesterol

Cholesterol Esterase



Cholesterol Oxidase

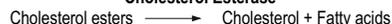


Peroxidase

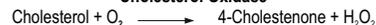


Measurement of LDL Cholesterol

Cholesterol Esterase



Cholesterol Oxidase



Peroxidase



EXPECTED VALUES

Species	LDL Cholesterol (mg/dl)
Dog	30-100
Cat	12-33
Cow	20-50
Buffalo	20-50
Horse	10-40
Pig	15-50
Sheep	14-44
Goat	14-44
Rabbit	12-40

It is recommended that each laboratory establish its own range as reference ranges may vary between laboratories.

PRESENTATION

REF	1126140040
Pack Size	40 ml
L1 LDL-D Reagent 1	30 ml
L2 LDL-D Reagent 2	10 ml
C Calibrator (for 1 ml)	1 No.

COMPOSITION

Goods Buffer 50mM; 4-AAP 14mM; CHE 4800 U; POD 4800 U; CHOD 3600 U; Magnesium Chloride Hexahydrate 6mM; Non Reactive Stabilizers, Detergents and Preservatives.

STORAGE/STABILITY

Contents are stable at 2-8°C till the expiry mentioned on the labels.

REAGENT PREPARATION

Reagents L1 and L2 are ready to use. Cap the bottles immediately after use and avoid contamination.

Calibrator : Reconstitute with 1 ml of D.W. Mix gently to dissolve the contents. Once reconstituted the calibrator is stable for 2 weeks at 2-8°C or 3 months at -20°C. Do not repeatedly thaw and refreeze.

SAMPLE MATERIAL

Serum or Heparinised plasma. Serum should be separated from clot as soon as possible. LDL-D is reported to be stable in serum, Heparinised plasma for 1 week (8 days) at 2-8°C.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimens, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

MATERIALS REQUIRED BUT NOT PROVIDED

Photometer analyzer with standard thermostatic cuvette holder, micropipette and appropriate laboratory equipment.

PROCEDURE

Wavelength / filter : 546 nm
 Temperature : 37°C
 Light path : 1 cm

Pipette into clean dry test tubes labelled as Blank (B), Calibrator (C) and Test (T)

Addition Sequence	B (ml)	C (ml)	T (ml)
LDL-D Reagent 1 (L1)	0.375	0.375	0.375
Calibrator	-	0.005	-
Sample	-	-	0.005
Mix and incubate for 5 min. at 37°C and add			
LDL-D Reagent 2 (L2)	0.125	0.125	0.125

Mix well and incubate for 5 min. at 37°C and read the absorbance of the Calibrator and the Test against Blank.

CALCULATIONS

$$\text{LDLc in mg/dl} = \frac{\text{Abs. T}}{\text{Abs. C}} \times \text{Conc. of calibrator}$$

QUALITY CONTROL

The following process is recommended for QC during the assay of LDL-D Cholesterol. *Define and establish acceptable range for your laboratory.

- Two levels of control (Normal and Abnormal) are to be run on a daily basis.
- If QC results fall outside acceptance criteria, recalibration may be necessary.
- Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

LOD: 2 mg/dl

LOQ: 6 mg/dl

Lower Limit: 2 mg/dl

Higher Limit: 1000 mg/dl

If the value exceeds this limit, dilute the sample 1 + 1 with normal saline and repeat the assay (Results x 2)

Interferences:

Sample when spiked with interferent such as upto 30 mg/dl Bilirubin, 500 mg/dl haemoglobin, 50 mg/dl Ascorbic Acid does not affect the ability of the kit to determine the LDL Cholesterol concentration.

Precision:

Within run

Within run	n	Mean	SD	% CV
Sample 1	10	61.9	1.75	2.82
Sample 2	10	102.0	1.83	1.80
Sample 3	10	147.3	1.51	1.03

Between run

Between run	n	Mean	SD	% CV
Sample 1	10	61.7	1.72	2.78
Sample 2	10	102.2	1.84	1.80
Sample 3	10	147.4	1.53	1.04

Method comparison:

Comparative studies were done to compare our reagent with another commercial LDL-D Cholesterol Assay. No significant differences were observed. Details of the comparative studies are available on request.

NOTE

Components from human origin in the calibrator have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

Do not use the reagents if there are particles or turbidity. Control sera are recommended to monitor the performance of assay procedures. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances. Do not use turbid, deteriorated or leaking reagents.

REFERENCES

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- Duncan and Prasse's Veterinary Laboratory Medicine: Clinical Pathology, Kenneth S. Latimer, ISBN Jane Wardrop, 6th Edition -2010.
- Clinical Biochemistry of Domestic Animals, Sixth Edition, 2008 by Kaneko J.J., Harvey J.W. & Bruss M.L.
- Data on file: Coral Clinical Systems.

System Parameters		
Reaction	: End Point	Interval : —
Wavelength	: 546 nm	Sample Vol. : 0.005 ml
Zero Setting	: Reagent Blank	Reagent Vol. : 0.500 ml
Incub. Temp.	: 37°C	Standard : See Calibrator Value
Incub. Time	: 5 min. + 5 min.	Factor : —
Delay Time	: ---	React. Slope : Increasing
Read Time	: ---	Linearity : 1000 mg/dl
No. of read.	: ---	Units : mg/dl

SYMBOL KEYS

 Store at 2-8°C	 Manufacturer	IVD <i>In vitro</i> Diagnostic Medical Device	L1 LDL-D Reagent 1	Direct Enzymatic
 Use by (Last day of stated month)	 Consult Instructions for use	LOT Batch Number	L2 LDL-D Reagent 2	Direct Enzymatic Method
 Date of Manufacture	REF Catalogue Number		C Calibrator (for 1ml)	



Coral Clinical Systems
 A Division of Tulip Diagnostics (P) Ltd.

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