Cholesterol Kit

CliniQuant - FSR

Trinder's Method, End Point

Meril Diagnostics

For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 Cholesterol Reagent	R2 Cholesterol Standard
CHOFSR-01	4 x 25ml	4 x 25ml	1 x 5ml
CHOFSR-02	4 x 50ml	4 x 50ml	1 x 5ml
CHOFSR-03	5 x 100ml	5 x 100ml	2 x 5ml

INTENDED USE

This reagent is intended for quantitative determination of Cholesterol concentration in human serum or plasma.

CLINICAL SIGNIFICANCE

Cholesterol concentration in serum depends on various factors, diet, bile and intestinal secretions and cells. Excess cholesterol can precipitate and result in the development of cholesterol gallstones. Measurement of serum cholesterol levels can serve as an indicator of liver function, intestinal absorption and coronary artery risk assessment.

PRINCIPLE OF THE METHOD

$$\text{Cholesterol ester} \xrightarrow{\text{Cholesterol esterase}} \text{cholesterol + fatty acid}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{Cholesterol oxidase}} \text{Cholest-4-en-3-one} + H_2O_2$$

$$2H_2O_2 + 4\text{AAP} + \text{Phenol} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine Dye} + H_2O$$

KIT COMPONENTS

Composition

R1 - Cholesterol Reagent : Tris buffer 41.27 mmol/l pH 6.4, Pipes buffer 20 mmol/l, 4-AAP 0.344 mmol/l, Cholesterol esterase > 750 U/l, Cholesterol oxidase > 750 U/l, Peroxidase > 1.5 KU/l, 4-hydroxybenzoic acid 10 mmol/l

R2 - Cholesterol Standard : 200 mg/dl, Cholesterol powder 2.0 g/l, Ethanol 20 ml/l, Triton X 100 150 ml/l

MATERIALS REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/ rack, heating bath, controls, saline.

REAGENT PREPARATION, STORAGE & STABILITY

Reagent is ready to use. Keep away from direct light sources.
Stability: up to expiration date on labels at 2-8 °C.
Stability since first opening of bottle: preferable within 60 days at 2-8 °C.

REAGENT DETERIORATION

1. Discard any turbid reagent if reagent absorbance exceeds 0.3 at 505 nm against distilled water.
2. Keep the Standard vial plugged after use, in order to avoid deterioration.

WARNINGS AND PRECAUTIONS

1. Reagent may contain some non-reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
2. Specimens should be considered infectious and handled appropriately.
3. Contamination by soap or glycerol will affect this assay.
4. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Use fresh unhemolysed serum. Serum or plasma should be separated from the cells, as soon as possible. Use heparin or EDTA as anticoagulant. Serum / plasma is stable for 7 days at 2-8 °C.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	End Point
Standard Conc.	200 (mg/dl)
Filter – 1 (nm)	505
Filter – 2 (nm)	620
Temperature	37 °C
Volume (µl)	500
Delay Time (Sec)	5
Reaction Direction	Increase
Reference Low	140
Reference High	250
Linearity Limit	750

CE
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TEST PROCEDURE

Dispense	Blank	Standard	Sample
Reagent 1	1ml	1ml	1ml
Distilled water	10 µl	-	-
Standard	-	10 µl	-
Sample	-	-	10 µl
Mix, incubate for 5 min at 37°C or 20 min at RT (+25 to +30°C). Read absorbance of standard (As) and samples (Ax) against reagent blank.			

RESULT CALCULATION

Serum/plasma:

Cholesterol mg/dl = Ax/As x concentration of Standard

SI conversion factor: 1 mg/dl x 0.0259 = 1 mmol/l

EXPECTED VALUES

Desirable: < 200 mg/dl	OR	<5.18 mmol/
Borderline high: 200 – 239 mg/dl	OR	5.18 - 6.19 mmol/l
High: ≥ 240 mg/dl	OR	≥ 6.22 mmol/l

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended Calibrator (BioCal) or the Standard included, calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

PERFORMANCE CHARACTERISTICS

1. Linearity

The linearity is up to 750 mg/dl or 19.4 mmol/l.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 1 mg/dl.

The limit of quantification is 3.5 mg/dl.

3. Interferences

No interference has been observed for the following

Hemoglobin up to 500 mg/dl; Bilirubin up to 15 mg/dl

Triglyceride up to 700 mg/dl

4. Precision

Intra-assay/ Within run precision

n = 20	Mean (mg/dl)	SD (mg/dl)	CV (%)
sample 1	94.38	0.20	0.21
sample 2	185.48	0.55	0.29

Inter –assay/Run to run precision

n = 20	Mean (mg/dl)	SD (mg/dl)	CV (%)
sample 1	89.96	2.62	2.91
sample 2	187.35	2.90	1.55

5. Methods Comparison

Comparison was done between reference Cholesterol Reagent and CliniQuant - FSR Cholesterol Reagent (test).

N = 36 $y = 0.974x + 6.677$

$r^2 = 0.994$

LIMITATIONS

Samples with values above 750 mg/dl should be diluted with 0.9% saline, re-run and results multiplied by dilution factor.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 1003 – 1008.

2. Data on file: Meril Diagnostics.

IFU/CHOFSR01/00

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Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged

EC REP Authorized European Representative in the European Community