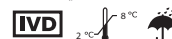


TRUEchemie CHOLESTEROL TEST KIT

(CHOD - POD)



for the quantitative determination of Total cholesterol in human serum or plasma

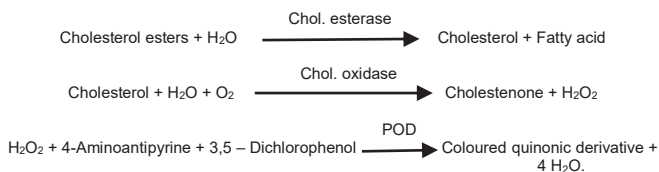
INTENDED USE

The TRUEchemie Cholesterol reagent test for the quantitative determination of total cholesterol in human serum (or) plasma.

INTRODUCTION

Cholesterol is a fatty substance found in blood, bile and brain tissue. It serves as a precursor to bile acids, steroids and vitamin D. The determination of serum cholesterol is a major aid in the diagnosis and classification of lipemias. Other conditions such as hepatic thyroid diseases influence cholesterol levels.

PRINCIPLE



PACK SIZE

Kit size	2 x 50 ml	2 x 100 ml
Cat. no.	ADX111	ADX112
Kit contents		
1) Cholesterol reagent	2 x 50 ml	2 x 100 ml
2) Cholesterol standard	1 x 5 ml	1 x 5 ml

REAGENTS COMPOSITION

1) Cholesterol reagent

Tris buffer pH 7.0	:	75 mmol/L
Phenol	:	6 mmol/L
4 - chlorophenol	:	0.2 mmol/L
4-Aminoantipyrine	:	0.5 mmol/L
Cholesterol Esterase	:	> 500 kU/L
Cholesterol Oxidase (CHOD)	:	< 300 kU/L
Peroxidase (POD)	:	> 1200 kU/L
Non reactive Stabilizers	:	

2) Cholesterol Standard	:	200 mg/dl
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STORAGE AND STABILITY

The components of the kit, stored at 2 - 8 °C, will remain stable until the expiry date stated on the label.

REAGENT PREPARATION

Ready to use reagents.

SAMPLE / SPECIMEN AND STORAGE

Test specimens should be serum free from hemolysis.

Cholesterol in serum is reported stable for seven (7) days at room temperature (18 - 25 °C) and six (6) months when frozen and properly protected against evaporation.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Specimens should be considered infectious and handled appropriately.
3. Avoid ingestion. DO NOT PIPETTE BY MOUTH.
4. The disposal of the residues has to be done as per local legal regulations.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes
2. Test tubes/rack
3. Timer
4. 37 °C heating block or water bath
5. Photometer capable of accurately measuring absorbance at 505 nm

TEST PROCEDURE

Wavelength	:	505 nm
Temperature	:	37 °C

Prewarm the reagent to reaction temperature

	Blank (ml)	Standard (ml)	Sample (ml)
Cholesterol reagent	1.000	1.000	1.000
Cholesterol standard	--	0.010	--
Sample	--	--	0.010

Incubate all tubes at 37 °C for 5 minutes. After incubation, zero the photometer with the reagent blank at 505 nm. Read and record the incubated standards and samples.

$$\text{Calculation} = \frac{\text{Sample OD}}{\text{Standard OD}} \times 200 \text{ mg Cholesterol/dl}$$

S.I. Units: (mg/dl) x 0.0259 = mmol/L

QUALITY CONTROLS

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

NORMAL VALUES

Desirable	:	up to 200 mg/dl (5.2 mmol/L)
Borderline High	:	200 – 239 mg/dl (5.2 – 6.21 mmol/L)
High	:	> 240 mg/dl (> 6.24 mmol/L)

It is strongly recommended that each laboratory establish its own normal range.

AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

CALIBRATION

The procedures are calibrated with the standard solution which is included with each series of tests. Its absorbance is used to calculate the results.

LIMITATIONS OF TEST

1. Linearity : up to 700 mg/dl
2. Sensitivity : 0.001 mg/dl.

For sample with higher concentration dilute with saline (NaCl 0.9%) 1:1, reassay and multiply the final results by 2.

INTERFERENCES

1. Anticoagulants such as fluoride and oxalate will result in false low values.
2. Hemoglobin values up to 200 mg/dl does not interfere.
3. Bilirubin levels up to 10 mg/dl does not interfere.
4. Interference from grossly icteric and heavily hemolyzed specimens is correctable by use of a serum blank.

SYSTEM PARAMETERS

Mode	:	End point
Std. Conc.	:	200
Wave length	:	505 nm
Units	:	mg/dl
Flow cell Temp.	:	37 °C
Blank	:	Reagent
Reagent volume	:	1.000 ml
Sample volume	:	0.010 ml
Incubation	:	5 min at 37 °C
Low Normal	:	0.0
High Normal	:	200

REFERENCES

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2. Holvey, D.N., ed. The Merck Manual of Diagnosis and Therapy. Merck and Co., Inc. Rahway, NJ (1972).
3. Allain, C.C., et al., Clin. Chem. 20:470 (1974).
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Index of symbols

Consult instructions for use	Catalogue number	Use-by date
For <i>in vitro</i> diagnostic use only	Batch code	Do not use if package is damaged
Temperature limit 2-8 °C	Keep away from sunlight	Keep dry
Manufacturer	Date of manufacture	
If device is non-sterile	Warnings / Precautions	

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