AGD
CliniPak

CHOLESTEROL

(CHOD/POD)

Code	Pack Size
AGDSP - CH160	8 X 20 mL
AGDSP - CH144	8 x 18mL
AGDSP - CH184	8 x 23mL

INTENDED USE

Cholesterol is a reagent set for in vitro quantitative determination of Total Cholesterol concentration in serum based upon enzy-matic colorimetric method.

CLINICAL SIGNIFICANCE

The determination of serum cholesterol is considered to be significant in coronary artery disease. Normal cholesterol levels are affected by stress, age, hormonal balance and pregnancy.

Increased Levels: Hyperlipoproteinemia, Hypothyroidism, nephrosis, diabetes mellitus and various liver diseases.

Decreased Levels: Hypocholesterolemia (low serum cholesterol is found in pernicious anemia, hemolytic jaundice, malnutrition acute infection and hyperthyroidism.

PRINCIPLE

The cholesterol esters of the sample are hydrolysed by cholesterol esterhydrolase (ChEH). 4-cholesten-3-one and H_2O_2 are then formed from the released free cholesterol by cholesterol oxidase (ChOD). A measurable Red quinonimine derivative which absorbs light at 505 nm is formed from hydrogen peroxide (H_2O_2) and 4 - Aminoantipyrine in the presence of phenol and peroxidase (POD)

$$\text{Cholesterol ester} + H_2O \xrightarrow{\text{CHE}} \text{Cholesterol} + \text{Fatty acids}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{CHO}} \text{4- Cholesten-3-one} + H_2O_2$$

$$2\,H_2O_2 + \text{Phenol} + \text{4-Aminoantipyrine} \xrightarrow{\text{POD}} \text{Red Quinone} + 4H_2O$$

PROCEDURE

Reagent + Sample + Incubation → Measurement
(300µL) (3 µL) (300sec) (505nm)

REAGENT COMPOSITION

Goods buffer pH 7.2	≈ 100 mmol/L
Cholesterol Oxidase	≈ 10 IU/L
Cholesterol Esterase	≈ 135 IU/L
Peroxidase	≈ 495IU/L
4 - Aminoantipyrine	≈ 0.5 mmol/L
Phenol	≈ 10 mmol/L

REAGENT STORAGE AND STABILITY

Cholesterol is a single reagent system ready to use The reagent is stable till the expiry date stated on the reagent bottle label when stored at 2-8°C protected from light.

SAMPLE

Collected sample using standard sampling tube fasting sample should be collected for Cholesterol assay.Preferably Serum sample can be used Anticoagulant such as heparin , EDTA or potassium oxalate plasma can be used.Do not use hemolysed or grossly contaminated samples.

BASIC PARAMETER

SHORT NAME	CHOL
NAME	Cholesterol
METHOD	CHOD/POD
ASSAY	End Point (2 point reagent blank)
MAIN WAVE	505nm
SUB WAVE	0
DECIMAL	2
UNIT	Mg/dL
R1 VOLUME	300µL
INCUBATION	36 secs
R2 VOLUME	0
SAMPLE VOLUME	3µL
INCUBATION	0 secs
MIXING SPEED	0
REACTION TIME (Delay)	260 secs
CHECK TIME (Read)	40 secs
LINEAR RANGE	0-1000
ABSORBANCE RANGE	0.0-2.5
DISCREPANCY	-
DETECTION SLOPE	-
DILUTION RATIO	6
SAMPLE VOLUME	50
CALIBRATION TYPE	Single Spot Linearity

*Enter calibrator value as per the lot of calibrator and method.

LINEARITY

Reagent is linear up to 1000 mg/dL.
Dilute the sample appropriately and re-assay
if Cholesterol concentration exceeds 1000mg/dL. Multiply result with dilution factor.

PRECISION

Reproducibility of within run determined using quality control sera as shown below.

Quality control material	Mean mg/dL	SD mg/dL	% CV
Low Control serum	144	1.2	1.59
High Control serum	272	1.4	1.67

REFERENCE NORMAL VALUE

109 - 202 mg/dL

QUALITY CONTROL

To ensure adequate quality control,it is recommended that the laboratory should use a normal and abnormal commercial reference control serum.The quality control material is used to check the function of reagents and the machine together.

LIMITATIONS & PRECAUTIONS

- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- Storage condition as mentioned on the kit to be adhered.
- Before the assay bring all the reagents to the room temperature.
- Avoid contamination of the reagent during assay process.
- Use clean glassware free from dust and debris.
- Reagent to sample ratio as mentioned above must be strictly adhered, as any changes it affects the factor and result.
- In case reagent comes in contact with eyes,immediately rinse with plenty of water and seek medical advice.

REFERENCES

- Lieberman, C., Ber. 18:1803 (1885).
- Burchard, H., Chem. Fentr. 61:25 (1890)

CE | IVD

AGD Biomedical Pvt. Ltd.
Site 2 : Plot No. W-29 E, TTC Industrial Area,MIDC,Thane Belapur Road, Rabale, Navi Mumbai,Thane, Maharashtra,(India)- 400701.
E : indiasales@agdbio.com
W : www.agdbio.com

ISO 13485:2016 ISO 9001:2015
EU REP
Obelis s. a.
Bd General Wahis
53 1030 Brussels Belgium
Phone : +32 2 732 59 54