MISPA CCXL / CX4 / CXL PRO

AGAPPE

CHOLESTEROL

5 x 65 mL
52019022

Intended Use
This reagent is intended for *in vitro* quantitative determination of Cholesterol in serum or plasma.
-CHOD-PAP methodology.
-Linear up to 600 mg/dL
-Contains LCF (Lipamic Clearing factor) which minimizes rerun

Clinical Significance
Cholesterol is the main lipid found in the blood, bile & brain tissues. It is also one of the most important steroids of the body & is a precursor of many steroid hormones. Two thirds of cholesterol present in the blood is esterified. The liver metabolizes the cholesterol & it is transported in the blood stream by lipoproteins.
Increased levels are found in hypercholesterolemia, hyperlipidemia, hypothyroidism, uncontrolled diabetes, nephritic syndrome & cirrhosis.
Decreased levels are found in malabsorption, malnutrition, hyperthyroidism, anaemia & liver diseases.

Principle
Enzymatic determination of total cholesterol according to the following reactions.

Cholesterol ester $+H_2O \xrightarrow{CHE}$ Cholesterol + fatty acids

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

$2H_2O_2$ +Phenol+4-Aminoantipyrine $\xrightarrow{POD}$ Red quinone $+ 4H_2O$

CHE : Cholesterol Esterase
CHO : Cholesterol Oxidase
POD : Peroxidase

Kit Components

Reagent/ Component	Product Code 52019022	Description	
Cholesterol Reagent	5 x 65 mL	Pipes buffer (pH 6.70)	50 mmol/L
		Phenol	24 mmol/L
		Sodium Cholate	0.5 mml/L
		Cholesterol Esterase	≥ 180 U/L
		Cholesterol Oxidase	≥ 200 U/L
		Peroxidase	≥ 1000 U/L
		4 – aminoantipyrine	0.5 mmol/L

Risk & Safety
Material Safety data sheets (MSDS) will be provided on request

Reagent Preparation
Cholesterol Reagent is ready to use.

Reagent Storage and Stability
The sealed reagents are stable upto the expiry date stated on the label, when stored at 2-8°C.

Open Vial Stability
Once opened the reagents are stable up to 90 days if contamination is avoided.

On-board Calibration Stability
Calibration is stable for 20 days.

Reagent Deterioration
Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Qualicheck Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution
To avoid contamination, use clean laboratory wares. Close reagent bottles immediately after use. Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.
This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management
Reagents must be disposed off in accordance with local regulations.

Sample
Fresh serum / plasma (Do not use lipemic or hemolysed sample), Urine (1/3 diluted)

Interferences
No interference for
Bilirubin up to 10 mg/dL
Haemoglobin up to 1000 mg/dL

Materials provided
Cholesterol Reagent

Reagents required but not provided
Multicalibrator (Product Code: 51610001), Qualicheck Norm (Product Code: 51601003), Qualicheck Path (Product Code: 51601002)

Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
mg/dL	mmol/L	x 0.026

Calibration
Agappe Multicalibrator (Product Code: 51610001) is recommended for calibration of the assay.

Quality control
It is recommended to use Qualicheck Norm (Product Code: 51601003) or Qualicheck Path (Product Code: 51601002) to verify the performance of the measurement procedure. Each Laboratory has to establish its own internal quality control scheme and procedures for corrective action if controls do not recover within the acceptable tolerance.

Reference Range
It is recommended that each laboratory should establish its own reference values. The following value may be used as guide line.
Serum, Plasma : 150 – 220 mg/dL
Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance
1. Linearity
The reagent is linear up to 600 mg/dL. If the concentration is greater than linearity (600 mg/dL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2. Comparison
A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of r^2= 0.998 and a regression equation of y = 1.0019x.

3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (mg/dL)	239.3	95.7	236.6	94.58
SD	7.11	3.23	4.96	2.89
CV(%)	2.97	3.37	2.10	3.06

Accuracy (mg/dL)		
Control	Expected Value	Measured Value
Control Level 1	263 ± 54	268
Control Level 2	105 ± 24	109
Qualicheck Norm	97 ± 18.0	94.4
Qualicheck Path	195± 15	195.7

4. Sensitivity
Lower detection Limit is 3.0 mg/dL

Bibliography
1. Allain C.C.*et al.,* Clin.Chem 20 (1974), 470

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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CE ISO 9001:2015
EN ISO 13485:2016