LiquiCHEK™

AGAPPE

CHOLESTEROL (S.L)

5 x 25 mL , 5 x 100 mL , 4 x 250 mL
11403002, 11403003, 11403007

Intended Use

This reagent is intended for *in vitro* quantitative determination of Cholesterol in serum or plasma.

- CHOD-PAP methodology
- Linear upto 600 mg/dL
- Contains LCF (Lipid clearing factor) which minimizes rerun

Clinical Significance

It 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 hypercholesterolaemia, hyperlipidaemia, hypothyroidism, uncontrolled diabetes, nephritic syndrome & cirrhosis.

Decreased levels are found in malabsorption, malnutrition, hyperthyroidism, anaemia & liver diseases.

Principle

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

$$\text{Cholesterol ester} + H_2O \xrightarrow{\text{Cholesterol esterase}} \text{Cholesterol} + \text{fatty acids}$$

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

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

Kit Components

Reagent/ Component	Product code: 11403002	Product code: 11403003	Product code: 11403007	Description
Cholesterol Reagent	5 x 25 mL	5 x 100 mL	4 x 250 mL	Pipes Buffer (pH 6.70) 50 mmol/L Phenol- 24 mmol/L Sodium Cholate 0.5 mmol/L 4 -Aminoantipyrine 0.5 mmol/L Cholesterol Esterase >180 U/L Cholesterol Oxidase >200 U/L Peroxidase >1000 U/L
Cholesterol Standard	1 x 4 mL	1 x 4 mL	1 x 4 mL	Cholesterol std. Conc. 200 mg/dL

Risk & safety

Material safety data sheets (MSDS) will be provided on request.

Reagent Preparation

Cholesterol Reagent & standard are 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^{0}C and protected from light.

Open Vial Stability

Once opened the reagent is stable up to 4 weeks at 2- 8^{0}C if contamination is avoided

On-board Calibration Stability

On board calibration stability is 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. Avoid direct exposure of working reagent to light.

Waste Management

Reagent must be disposed off in accordance with local regulation.

Sample

Fresh serum / plasma (free of haemolysis)

Interferences

No interference for

Bilirubin up to	10 mg/dL
Ascorbic acid up to	50 mg/dL
Haemoglobin up to	1000 mg/dL

Materials Provided

Cholsterol Reagent & Standarad.

Materials required but not provided

- Pipettes& Tips
- Test Tubes & racks
- Timer
- Incubator
- Analyzer

Test Parameter

Mode of Reaction	End point
Slope of reaction	Increasing
Wavelength I	505 (492 -550) nm
Wavelength II	630 nm
Temperature	37^{0}C
Standard Concentration	200 mg/dL
Blank	Reagent
Linearity	600 mg/dL
Incubation time	5 min
Sample volume	10 µL
Reagent volume	1000 µL
Cuvette	1 cm light path

Application parameters for various instrument are available. Please contact customer support department for specific information.

Unit Conversion

Unit (Conventional)	Unit (SI)	Conversion to SI unit
mg/dL	mmol/L	x0.026

Calibration

Agappe multicalibrator is recommended for calibration of this assay on fully auto analyzers.

Provided Standard is recommended for calibration of this assay on semi auto analyzers.

Procedure notes

Laboratory procedure For Semi Auto			
	Blank	Standard	Sample
Working Reagent	1000 µL	1000 µL	1000 µL
Standard	-	10 µL	-
Sample	-	-	10 µL
Mix, and incubate for 5 min.at 37^{0}C. Measure the absorbance of sample and standard against reagent blank			

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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REV. NO.: ADL/IFU/CHO/LIQ/R02

CE ISO 9001 : 2015
EN ISO 13485: 2016

Calculation

Cholesterol Conc. (mg/dL) = $\frac{\text{Absorbance of sample}}{\text{Absorbance of standard}}$ x 200

Quality control

It is recommended to use Agappe Qualicheck Norm and Path(11601001) to verify the performance of the assay.Each laboratory has to establish its own internal quality control scheme and procedure for corrective action,if control do not recover within the acceptable range.

Reference Range

It is recommended that each laboratory has to 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 finding of patient for interpretation and diagnosis.

Performance

1. Linearity

This reagent is linear upto 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		
	Control Level 1	**Control Level 2**
n	20	20
Mean (mg/dL)	239.3	95.7
SD	7.11	3.23
CV(%)	2.97	3.37

Inter Run		
	Control Level 1	**Control Level 2**
n	20	20
Mean (mg/dL)	236.60	94.58
SD	4.96	2.89
CV %	2.10	3.06

Accuracy (mg/dL)		
Control	**Expected Value**	**Measured Value**
Control Level 1	263 ± 54.0	268
Control Level 2	105 ± 24.0	109
Qualichek Norm	97 ± 18.0	94.4
Qualichek Path	195 ± 15.0	195.7

4.Sensitivity

Lower detection Limit is 3 mg/dL.

Bibliography

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

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