

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

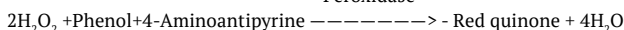
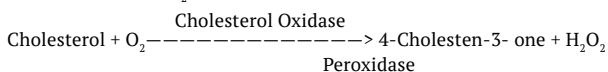
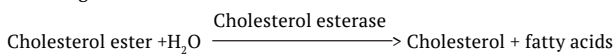
It is the main lipid found in the blood, bile & brain tissues. It is also one of the most important steroids of the body & is a precursor of many steroid hormones. Two thirds of cholesterol present in the blood is esterified. The liver metabolizes the cholesterol & it is transported in the blood stream 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.



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°C and protected from light.

Open Vial Stability

Once opened the reagent is stable up to 4 weeks at 2- 8°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

Cholesterol 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°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°C. Measure the absorbance of sample and standard against reagent blank | | | |

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE **i** SEE PACKAGE INSERT FOR PROCEDURE **LOT** LOT NUMBER **M** MANUFACTURER'S ADDRESS **M** MANUFACTURING DATE **E** EXPIRY DATE **T** TEMPERATURE LIMIT

Calculation

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

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 |
| Qualicheck Norm | 97 ± 18.0 | 94.4 |
| Qualicheck 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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