

ANA BIO ISP CHOLESTEROL

(CHOD-POD Method)

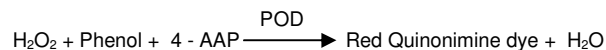
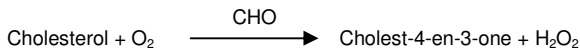
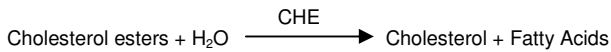
For Miura Instruments

Intended Use

Cholesterol is a reagent kit used for the determination of total cholesterol based on enzymatic method using cholesterol esterase, cholesterol oxidase and peroxidase.

Principle

Cholesterol esterase (CHE) hydrolyses cholesterol esters into free cholesterol and fatty acids. In the second reaction cholesterol oxidase (CHO) converts cholesterol to cholest-4-en-3-one and hydrogen peroxide. In presence of peroxidase (POD), hydrogen peroxide oxidatively couples with 4-aminoantipyrine and phenol to produce red quinonimine dye. The intensity of the red colour is proportional to the amount of total cholesterol present in the specimen.



Components & Concentration of Reagents

| Reagent | Component | Concentration |
|----------------|---|---------------|
| Enzyme Reagent | Goods Buffer PH 6.8 | 100 mmol/L |
| | Phenol | 10 mmol/L |
| | 4-AAP | 0.5 mmol/L |
| | CE | ≤300 U/L |
| | COD | ≤100 U/L |
| | POD | ≤500 U/L |
| | Stabilizers, excipients & surface active agents | |

Reagent storage and stability

The kit should be stored at 2° - 8°C and is stable till the expiry date indicated on the label. **DO NOT FREEZE THE REAGENT.**

Reagent Preparation

Liquid reagent ready for use. After opening the reagent is stable for 30 days if closed, stored at 2° - 8°C, and protect from direct light. Do not mix different batches.

Specimen collection and preservation

Blood should be collected in a clean and dry container. Fasting blood is preferred for cholesterol assay. Cholesterol in the serum is stable for 7 days when stored at 2°-8°C and 60 days when stored at -20°C

Automation

This kit, though developed and manufactured to be used as manual assay and with I.S.E. Miura Analyzer, can be used also with other analyzers able to meet the specifications indicated in section "Reaction conditions – Test procedure" Application sheets are available for automatic instruments.

All applications not explicitly approved by KDPL. Cannot be guaranteed in terms of performance, and must there be established by the operator.

Calibration

For Calibration use the "Multicalibrator"

Calibration Stability

For the instrumentation series Miura, the calibration is recommended to be done every 10 days.

Materials required but not supplied in the kit

Calibrators and controls

Assay guidelines for Analyzer I.S.E. Miura

| | |
|--------------|-------------|
| Analyte Name | Cholesterol |
| Method Code | CHO |
| Type | End-Point |
| Unit | mg/dl |

| | | |
|-------------------|-----------------|------|
| Filter F1 | 505 nm | |
| Blank in | Use | |
| Step | Reaction Volume | U.M. |
| Volume reagent R1 | 200 | μl |
| Sample Volume | 2 | μl |
| Final Incubation | 300 | Sec. |

Normal range

- Guidance value for Children : 90 - 160 mg/dl
- Guidance value for Adult : 130 - 200 mg/dl

Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitation

Reaction is linear up to 1000 mg/dl. If the cholesterol value exceeds 1000 mg/dl, then dilute the specimen suitability with normal saline and repeat the assay. In such case the results obtained should be multiplied by dilution factor to obtain correct cholesterol value.

Quality Control

To ensure adequate quality control measures, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware, Wavelength setting, Expiration date of reagents and accuracy of prob aspiration.

Accuracy-Recovery

Cholesterol added to a serum matrix containing known amounts of Cholesterol gave an average recovery of 96%.

Interference

The high dilution of the sample with the reagent reduces to a minimum the interference by lipids. Bilirubin below 5.8 mg/dl does not interfere in the reaction. Haemoglobin interferes at concentrations above 10.0 g/L.

Precision of the Method

| Within-run | | | | | |
|-------------|-------|--------|------|----------|---------|
| Range | U.M | Mean | S.D. | C.V. (%) | No. run |
| Low | mg/dl | 129.75 | 3.34 | 2.57 | 20 |
| High | mg/dl | 205.85 | 3.50 | 1.70 | 20 |
| Between run | | | | | |
| Range | U.M | Mean | S.D. | C.V. (%) | No. run |
| Low | mg/dl | 130.19 | 3.47 | 2.67 | 60 |
| High | mg/dl | 204.45 | 3.71 | 1.82 | 60 |














Sensitivity

At 505 nm a concentration of 7.0 mg/dl of Cholesterol can estimate.


References

- Richmond,W.Clin. Chem. 19, 1350 (1973).
- Allain C.C et al, Clin. Chem., 20, 470 (1974).
- Tarbutton P.N., Gunter C.R., Clin. Chem, 20,724(1974).
- Richmond,W. scan. J. Clin. Lab. Invest. 29, Suppl. 26, Abst. 3.25 (1972).
- Young D.S. et al, 21, D (1975).

Symbols

| | | | |
|--|----------------------|---|--------------------------|
|  IVD | In Vitro Diagnostics |  | Caution |
|  LOT | Batch No. |  | Product Expiry Date |
|  CONT | Content |  | Manufactured By |
|  | Read Instructions |  | Date of Manufacture |
|  | Storage Temperature |  | Keep Dry |
|  REF | Catalogue No. |  | Fragile |
| | |  | Keep away from sun light |



 **KEE DIAGNOSTICS PVT LTD**
(Formerly known as Kee GAD Biogen Pvt. Ltd.) .
CIN: U24231DL2004PTC128343 .
A subsidiary of KEE PHARMA LTD
A-8 . 3RD FLOOR. NARAINA INDUSTRIAL
AREA, PHASE 2 . NEW DELHI 110028.
W. www.keediagnosics.in.
E. info@keediagnosics.in, T. 011 43136000.