Reflotron® Cholesterol

Appendix 4

REF 10745065 30 tests

English

Intended use
Test for the quantitative determination of cholesterol in blood, serum or plasma with Reflotron systems.

Summary
Cholesterol is a steroid with a secondary hydroxyl group in the C-27 position. It is synthesized in the liver and in the wall of the intestines. About three quarters of the body’s cholesterol is synthesized by the tissues while one quarter comes from the diet. Determination of cholesterol is used to screen for an atherogenic risk and in the diagnosis and treatment of diseases with increased cholesterolaemia and disorders of lipid and lipoprotein metabolism.

Test principle
After application to the test strip, the sample flows into the reaction zone, where, in the case of blood samples, the separation of the erythrocytes from the plasma occurs. The cholesterol esters are hydrolyzed into the corresponding fatty acid and cholesterol, which are then oxidized to cholestane and hydrogen peroxide in the presence of oxygen. In a further reaction step catalyzed by the enzyme peroxidase, the hydrogen peroxide reacts with a red indicator, resulting in a blue dye which is proportional to the cholesterol concentration in the sample:

\[
\text{cholesterol ester} + \text{H}_2\text{O} \rightarrow \text{cholesterol} + \text{RCH}_2\text{OH}
\]

\[
\text{cholesterol} + \text{H}_2\text{O} \rightarrow \text{cholestane} + \text{H}_2\text{O}
\]

\[
\text{H}_2\text{O}_2 + \text{indicator} \rightarrow \text{dye} + \text{H}_2\text{O}
\]

The cholesterol concentration (proportional to the dye formed) is measured at a wavelength of 480 nm at 25°C, and is displayed after about 150 seconds in mg/dl or mmol/L.

Reagents
Components per test: Cholesterol esterase (microorganism) ≥ 0.29U/l; cholesterol oxidase (Biosint. E. coli) ≥ 0.15U/l; PO2 (dehydrazinol) ≥ 0.59U; 3,3',5,5'-tetramethyl-benzidine 19.3 µg/l; buffer.

Precautions and warnings
For in vitro diagnostic use. For the normal precautions required for handling all laboratory reagents. Safety data sheet available for professional user on request. Disposal of all waste material should be in accordance with local guidelines. Avoid any contact to the application zone of a test strip (i.e., during pointing of sample).

Reagent handling
Test strips are ready for use.

Storage and stability
Store at 2-30°C. Do not use the test strip after the specified expiry date.

Specimen collection and preparation
Capillary blood: whole blood collected in standard sample collection tubes; serum; heparinized or EDTA blood, or heparinized or EDTA-plasma. The trash capillary or venous blood immediately after collection. EDTA- or heparinized plasma kept in closed containers should be used within 4 hours if stored at a temperature of 20-25°C, or within 8 hours if stored at a temperature of 0-8°C. Shake the sample before performing the test to ensure homogeneous distribution of the cellular components.

If cooled single-use containers or capillary pipettes are used, please observe the stability data given by the manufacturer.

EDTA- or heparinized plasma kept in closed containers should be used within 4 hours if stored at a temperature of 20-25°C, or within 12 hours if stored at a temperature of 4-8°C. Do not freeze the samples. Compared to serum, results of up to -6% are obtained with EDTA blood, or plasma samples.

Sample volume: 20 µL

Materials provided
1 container with 30 test strips

Materials required (but not provided)
• Reflotron instrument
• Reflotron pipette
• Reflotron pipette tips
• Reflotron capillary tubes
• Reflotron Precision U, Reflotron Precision II, or Reflotron Clean + Check
• General laboratory equipment

Assay procedure
For optimum performance of the assay, follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator’s manual for analyzer-specific assay instructions.

1. Remove a test strip from the container. Tightly recap the container immediately after removing a test strip.

2. Peel off the aluminium protective foil, taking care not to bend the test strip.

3. All Reflotron tests require a sample volume of 30 µL.

4. Apply the required volume of sample onto the centre of the red application zone, using a pipette (e.g., Reflotron pipette) – being careful not to touch the application zone. Avoid air bubbles.

5. Place the test strip in the instrument. After 60 seconds read-out the samples show the

Calibration
The function curve for the Reflotron Cholesterol assay for converting reflectance values into concentrations is defined for each lot using the cholesterol (CHOD-PAP) method from Roche Diagnostics standardized to GC/MS. The parameters of the curve are automatically transferred to the instrument via the magnetic strip during testing.

Quality control
For quality control, use Reflotron Precision U, Reflotron Precision II, or Reflotron Clean + Check.

The control intervals and limits should be acquired to each laboratory’s individual requirements. Values obtained should fall outside the defined limits.

Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Follow the applicable government regulations and local guidelines for quality control.

Calculation
The cholesterol concentration is calculated automatically from the measurements taken, and function and conversion factors read from the magnetic strip on the lower face of each test strip. The cholesterol concentration is displayed in mg/dl or mmol/L, depending on whether the instrument has been set to conventional or SI units.

Conversion factor: mg/dl x 0.0258 – mmol/L.

Limitations – Interferences
The following list has no influence on the results in the concentration ranges tested (interference: recovery ≥ 10% of baseline): physiological concentrations of bilirubin, lipemic sera; haemolysis up to 50%, haemoglobin up to 1 %, and 44 further drugs.

High concentrations of the following substances can lower the measured cholesterol values: aminoantipyrine, eserine, acid, L-lysine, pentoxyfylline, glutathione, methyldopa, nalidixic acid.

For diagnostic purposes, the results should always be assessed in conjunction with the patient’s medical history, clinical examination and other findings.

Measuring range
100–500 mg/dl, or 2.58–12.9 mmol/L.

If the measured cholesterol value is above the measuring range for the Reflotron Cholesterol assay, the sample may be diluted 1:1 with serum or plasma having a known cholesterol concentration C. The true cholesterol value C can be calculated from the measured cholesterol concentration C by using the following formula: C = 2 Cm/Cp.

Expected values
< 200 mg/dl, or < 5.2 mmol/L.

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data
The data for the Reflotron Cholesterol assay were determined in evaluation studies. The majority of the test results were within the given ranges.

Precision
Repeatability (within-run precision): CV (coefficient of variation) 3.0 % in the normal range, 3.7 % in the pathological range; sample material: heparinized blood.

Intermediate precision (between-run precision): CV 2.3 % in the normal range, 2.4 % in the pathological range; sample material: control sera.

Method comparison
A comparison of the Reflotron Cholesterol assay (y) with the CHOD-PAP method (x) gave the following correlations:

y = 0.9638x - 1.373; n = 102; r = 0.972; sample material: heparinized blood.

References

Last update: 2010-06

Symbol table

Cathode number
LOT Batch code/Lot number
WD In vitro diagnostic medical device
Manufacturer
Use by
Temperature limitation (Store at)
Consult Instructions for use
This product fulfills the requirements of the European Directive 93/42/EEC for in vitro diagnostic medical devices

Significant additions or changes are indicated by a change bar in the margin.

REF 10745065 30 Tests

Deutsch

Anwendungsziel
Test zur quantitativen Bestimmung von Cholesterin in Blut, Serum oder Plasma mit Reflotron Systemen.

Zusammenfassung

Anordnung des Analysenablaufs
Blut, Serum oder Plasma wird in Reflotron Pipette oder Reflotron Pipette IV gesetzt. Das Pipette wird auf das Reflotron System gestellt und mit dem Blut oder Serum tropfenweise versorgt. Das System misst die Cholesterinwerte durch eine spezifische chemische Reaktion, die die Cholesterolester in freies Cholesterol spaltet. Das freie Cholesterol wird dann durch eine Peroxidase in ein endständiges Produkt umgewandelt, das die Absorption bei 480 nm erzeugt.

Qualitätskontrolle
Die Qualität der Messung wird durch die Verwendung von Qualitätskontrollen gewährleistet, die in der Meßkette von Reflotron eingebaut sind. Die Resultate werden durch die Rechnung des Instruments automatisch berechnet und anzeigt.
Intended use
Test for the quantitative determination of triglycerides in blood, serum or plasma with Reflotron®.

Presentation
Pack of 30 test strips, REF 1 0745049

Clinical aspects
Triglycerides are esters of the triglyceric alcohol glycerol with 3 long-chain fatty acids. They are partly taken up with the diet, partly synthesized in the liver. Triglycerides are determined for early detection of a risk of atherosclerosis, for classification of hyperlipoproteinemia and for monitoring lipid-lowering diet therapy and pharmacotherapy.

Test principle
After application to the test strip, the sample flows into the reaction zone, in the case of blood after separation of the erythrocytes from the plasma. The triglycerides are oxidized in an enzymatic reaction. Various reaction steps then lead to the formation of H₂O₂. This oxidizes a redox indicator to a blue dye in a reaction catalyzed by the enzymes peroxidase.

triglycerides + H₂O → esterase
glycerol + 3 ROOH

glycerol kinase

glycerol + ATP → glycerol-3-phosphate + ADP

ATP

glycerol-3-phosphate + O₂ → glycerol phosphate oxidase
dihydroxyacetone phosphate + H₂O

H₂O₂ + indicator → PPD → dye + H₂O

At a temperature of 37°C the dye formed is measured at 842 nm and the triglyceride concentration displayed after about 180 seconds in mg/dl or mmol/l depending on how the instrument has been set.

Components per test-estatine (microorganisms rec.): 0.63 µl L⁻¹ glycerol kinase (Bacillus stearothermophilus) ≥ 9.6 U L⁻¹; 0.06 µl L⁻¹ glycerol phosphate oxidase (Micrococcus rec.) ≥ 0.07 µl L⁻¹; 0.01 µl L⁻¹ iodonitrotetrazolium ≥ 0.055 IU L⁻¹; 0.05 µl L⁻¹ 5-methyl-2-(3,5-dimethoxy-4-hydroxymethyl)-isoxazole dihydrochloride (indicator); 0.38 µg ml⁻¹ buffer.

Precautions and warnings
For in vitro diagnostic use. Please observe the usual precautions for handling laboratory reagents.

Storage and shelf-life
Store at 0°C to +20°C. Under these conditions the tests can be used up to the expiry date printed on the pack or container. After removing a test strip, be sure to re-stopper the container immediately otherwise exposure to dust, humidity etc. may render the test strips unusable.

Sample collection and treatment
Capillary blood: whole blood collected in standard sample collection tubes, as well as serum prepared from this, heparinized or EDTA-blood or heparinized or EDTA-plasma.

Whole blood or various blood immediately after collection.

EDTA- or heparinized blood kept in closed containers should be used within 9 hours. After precipitation of the cellular components the supernatant plasma may be used if care is taken not to shake the specimen.

If collected single-use containers or capillary pipettes are used, please observe the stability data given by the manufacturer.

Serum and EDTA- or heparinized plasma kept in closed containers is stable for 8 hours at +2 to +6°C and for 24 hours at +4°C to +4°C. Do not freeze specimens.

Notes: Limitations of the procedure – interference

Interferences with the measurement: blood containing drug substances, examples: salicylates, glutethimide, disulfiram, trimethadione, propranolol, chlordiazepoxide.

Calibration
The function curve for Reflotron Triglycerides, for converting reflectance values into concentrations, is defined for each lot, using the Triglyceride (EPO-PAP) method of Roche Diagnostics. The data are automatically programmed into the instrument during testing.

Testing procedure
Additional materials required (not supplied): Reflotron instrument; Reflotron Pipette and pipette tips or capillary pipette, controls, usual laboratory equipment for red blood cell

Unwrap the strip (a), taking care not to bend it.

Using the Reflotron Pipette, for example, draw sample material into the pipette (pipetting bubbles) and apply as a drop to the centre of the red application zone (b) – being careful not to touch the application zone (b) with the pipette tip (c). Secure the required volume of specimen for application, 30 µl (see illustration).

With the sliding cover or flap open, place the test strip on to the guide within 15 sec and slide forward horizontally until it locks into place (c). Close the sliding cover or flap.

The instrument displays "TG" to confirm that it has correctly read in the test-specific magnetic code. The display shows the number of seconds left before the result is displayed. The triglyceride concentration is calculated automatically from the readings taken using a function and conversion factors that are entered in the instrument via the magnetic strip on the underside of each test strip. The triglyceride concentration is displayed in mg/dl or mmol/l depending on whether the instrument has been set to show conventional or SI units.

Remove the used test strip from the Reflotron and dispose of it according to your laboratory's procedure.

Reference range
≤ 209 mg/dl or ≤ 2.32 mmol/l

Conversion factor: mg/dl → 0.0114 = mmol/l

The definition of hypertriglyceridemia is problematic as concentrations can considerably exceed the reference range even within a group of healthy subjects and because of the large physiological fluctuations

It is up to each laboratory to check that the reference ranges are appropriate to its patient group, and to establish its own reference ranges if necessary.

For diagnostic purposes the triglyceride results should always be evaluated in combination with the history, the clinical examination and the results of other examinations and tests carried out.

Measuring range and dilution
Measuring range: 70 – 600 mg/dl or 0.80 – 6.86 mmol/l

If the measured triglyceride concentration is above the measuring range for Reflotron Triglycerides (indicated by > in front of the result), the serum or plasma sample can be diluted with physiological saline in a ratio of 1:1. The true triglyceride concentration C can be calculated from the displayed triglyceride concentration Cₐ using the following formula: C = Cₐ x A

Quality control
For quality control, use Reflotron Standards or Reflotron Check to meet individual laboratory requirements or to comply with regulations. The results must be within the prescribed ranges. Each laboratory must specify corrective measures to be applied in the event of values being out of range.

Performance characteristics
The data for Reflotron Triglycerides were determined in series of tests. The majority of the data for the test were within the given ranges.

Repeatability (within-series precision): CV (coefficient of variation) 3.6 % in the normal range, 1.9 % in the pathological range; sample material: serum.

Reproducibility (day-to-day reproducibility): CV 2.3 % in the normal range, 2.9 % in the pathological range; sample material: control sera.

Accuracy
accuracy of comparison: 0.01 ml in the normal range, ± 1.0 % in the pathological range; sample material: serum, EDTA-blood, EDTA-plasma.

For an explanation of the symbols used and a list of references please refer to the end of this insert.

Last updated: 2010-05

DE

Anwendungszweck
Test zur quantitativen Bestimmung von Triglyceriden in Blut, Serum oder Plasma mit Reflotron® Messgerät.

Handelsform
Packung mit 30 Reagenzträgern, REF 1 0745049

Klinische Anwendung

Testprinzip
Im vorliegenden Referenz Triglycerid-Test hält die anfängliche Probe, bei Blut unter Abtrennung der Erythrozyten, auf dem Reflotron-Reagenzträger in der Reaktionszone. Die Triglyceride werden in einer enzymatischen Reaktion gespalten, durch verschiedene Reaktionsprodukte, die Bildung von H₂O₂. Dieses oxidiert unter der katalytischen Wirkung des Enzmys Peroxidase einen Redoxindikator zu einem
**Intended use**

Test for the quantitative determination of HDL cholesterol in EDTA plasma with Reflotron.

**Presentation**

Pack of 30 test strips, Ref 1208756

**Clinical aspects**

HDL (high density lipoprotein) is responsible for transporting cholesterol from the peripheral cells back to the liver. There the cholesterol is converted into bile acids which are eliminated into the intestine via the bile ducts. Monitoring of HDL cholesterol is clinically important as there is an inverse relationship between the HDL cholesterol and the risk of atherosclerotic disease. Elevated concentrations of HDL have a protective effect against coronary heart disease while diminished levels of HDL cholesterol, particularly in combination with elevated triglycerides, constitute an increased cardiovascular risk.

**Test principle**

The cuvettes sulfite Mg* on the test strip precipitates the chylomicrons, VLDL and LDL, leaving HDL in the sample. The cholesterol concentration of this HDL is then determined enzymatically. The cholesterol esters are cleaved into the corresponding fatty acid and cholesterol which is then oxidized to cholesterylone and hydrogen peroxide in the presence of oxygen. In a further reaction step catalyzed by the enzyme peroxidase, the hydrogen peroxide catalyzes a redox indicator, resulting in a blue dye which is proportional to the cholesterol concentration in the sample.

\[
\text{cholesterol ester} \rightarrow \text{cholesterol + RCDOH} \\
\text{cholesterol + } \text{O}_{2} \rightarrow \text{cholesterol + HCOOH} \\
\text{H}_{2} \text{O} + \text{H}_{2} \text{O} \rightarrow \text{POD} \rightarrow \text{POD} + \text{H}_{2} \text{O}
\]

The instrument displays HDL if it has correctly read the test-specific magnetic code. The display shows the number of seconds left before the result is displayed. The HDL cholesterol concentration is calculated automatically from the readings taken using a function and conversion factors that are stored in the instrument via the magnetic strip on the underside of the test strip. The HDL cholesterol concentration is shown in mg/dl or mmol/l depending on whether the instrument has been set to display conventional or SI units.

**Reference range**

Guidelines of the National Cholesterol Education Program (NCEP):
- < 40 mg/dl or < 1.04 mmol/l low HDL cholesterol (higher risk for developing CVD)
- < 60 mg/dl or 2.6 mmol/l high HDL cholesterol (lower risk for developing CVD)

**Measuring range**

Measuring range: 10 - 100 mg/dl or 0.26 - 2.6 mmol/l

**Quality control**

For quality control, use Reflotron Precision HDL or Reflotron Check to meet most individual laboratory requirements or to comply with regulations. The results must be within the prescribed ranges. Each laboratory must specify corrective measures to be applied in the event of values being out of range.

**Performance characteristics**

The HDL cholesterol were determined in series of tests. The majority of the data for the test were within the given ranges. Reproducibility (within-run): CV 0.2% in the low range, 2.2% in the elevated range.

**Storage and shelf-life**

Store at -2°C to +20°C. Under these conditions the test can be used up to the expiry date printed on the pack or container. After removing a test strip, be sure to re-insert the container immediately otherwise exposure to dust, humidity etc. may render the test strips unusable.

**Sample collection and treatment**

Obtain EDTA plasma from EDTA citrullin blood or EDTA blood collected with standard blood collection tubes. Only fresh EDTA plasma may be used for the test. The test should be performed as soon as possible after collection of the sample. The increase in the recovery after 24 hours is about 4%.

Do not use any other specimen material.

**Notes; limitations of the procedure - Intercalibration**

Total concentrations of calcium cholesteral can lead to measurement of diminished HDL concentrations.

The following had no influence on the results in the concentration range tested (correlation: recovery ± 1.0% of baseline): haemoglobin up to approx. 75 mg/dl (0.65 mmol/l), bilirubin concentrations up to 6 mg/dl (103 μmol/l), cholesterol up to 350 mg/dl (9.1 mmol/l), triglyceride concentrations up to 400 mg/dl (4.59 mmol/l), ascorbic acid up to 30 mg/dl (0.724 μmol/l), total protein contents between 4.5 and 9 g/l (45-90 g/l) and 27 further drugs tested.

**Calibration**

The function curve for Reflotron HDL Cholesterol, for converting reflectance values into concentrations, is defined for each lot, using the homogeneous HDL Cholesterol plus method from Roche Diagnostics. The data are automatically programmed into the instrument during testing.

**Testing procedure**

Additional materials required (not supplied): Reflotron instrument; Reflotron Pipette and pipette tips for capillary pipette, controls, test laboratory equipment, for collecting blood.

Before carrying out the test, read the Reflotron manual and be sure that you are familiar with the instrument's operation.

**Switch on the instrument**

**Insert test strip into the container**

The instrument displays HDL if it has correctly read the test-specific magnetic code. The display shows the number of seconds left before the result is displayed. The HDL cholesterol concentration is calculated automatically from the readings taken using a function and conversion factors that are stored in the instrument via the magnetic strip on the underside of the test strip. The HDL cholesterol concentration is shown in mg/dl or mmol/l depending on whether the instrument has been set to display conventional or SI units.

**Remove the used test strip from the Reflotron and dispose of it according to your laboratory’s procedure.**

**Anwendungszweck**

Test zur quantitative Bestimmung von HDL-Cholesterin in EDTA-Plasma mit Reflotron Messgeräten.

**Händlerschein**

Pakung mit 30 Reagenzträgern, Ref 1208756

**Klischee Aspekte**


**Teststeplauf**

Durch das auf dem Reagenzträger enthaltene Destressmittel Mg2+ werden Chylomicronen, VLDL und LDL unspezifisch. In der Probe verbleibt HDL. Die Cholesterinbestimmung automatisch bestimmt wird.
PRINCIPLE OF THE METHOD

Low density lipoproteins (LDL) in the sample precipitate with polyvinyl sulphate. Their concentration is calculated from the difference between the serum total cholesterol and the cholesterol in the supernatant after centrifugation. The cholesterol is spectrophotometrically measured by means of the coupling reactions described below:

- Cholesterol esters + H₂O → cholesteryl + fatty acid
- Cholesterol + 15 O₂ + H₂O → cholesteryl + H₂O₂

₂H₂O₂ + 4 - Aminocoumarin + Phenol → Quinomeline + 4 H₂O

CONTENTS AND COMPOSITION

A. Reagent, 1 x 20 mL, Polystyrene sulphate 3 g/L, polyethylene glycol 3 g/L.

STORAGE

Store at 2-8°C.

Reagent is stable until the expiry date shown on the label when stored tightly closed and if contamination is prevented during that time.

Indications of deterioration:
- Reagent: Presence of particulate material, turbidity.

ADDITIONAL REAGENTS

This precipitating reagent is to be used together with this cholesterol reagent contained in any of the Biosystems cholesterol kits (cod. 11065, 11066, 11506, 11839).

REAGENT PREPARATION

Reagent is provided ready to use.

ADDITIONAL EQUIPMENT

- Desktop centrifuge
- Thermostatic water bath at 37°C
- Analyser, spectrophotometer or photometer able to read at 600 ± 20 nm

SAMPLES

Serum collected by standard procedures.

LDL cholesterol in serum is stable for 24 hours at 2-8°C.

PROCEDURE

Precipitation

1. Pipette into labelled centrifuge tubes (Note 1):
   - Sample
   - Reagent (A) (Cholesterol/LDL kit)

2. Mix thoroughly and let stand for 15 minutes at room temperature.

3. Centrifuge at a minimum of 4000 rpm for 15 minutes.

4. Carefully collect the supernatant (Note 2).

Colorimetry

5. Bring the Reagent (Cholesterol kit) to room temperature.

6. Pipette into labelled test tubes: (Note 3)

   Blank
   Sample
   Standard

   Sample
   Standard

- Distilled water
- Cholesterol Standard (5)
- Sample supernatant
- Reagent (A) (Cholesterol kit)

7. Mix thoroughly and incubate the tubes for 30 minutes at room temperature (16-20°C) or for 10 minutes at 37°C.

8. Measure the absorbance (A) of the Standard and Sample at 500 nm against the Blank. The colour is stable for at least 30 minutes.

CALCULATIONS

The cholesterol concentration in the supernatant is calculated using the following general formula:

\[ \frac{A_{\text{Sample}}}{A_{\text{Standard}}} = \frac{C_{\text{Sample}}}{C_{\text{Standard}}} \]

If the Cholesterol Standard, provided in the Cholesterol kit, has been used to calibrate (Note 4):

\[ \frac{A_{\text{Sample}}}{A_{\text{Standard}}} = \frac{C_{\text{Sample}}}{C_{\text{Standard}}} \times \frac{200 \times 2}{2 \times \text{mg/dL cholesterol in supernatant}} \]

The LDL cholesterol concentration in the sample is calculated as follows:

\[ \text{LDL cholesterol} = \text{total cholesterol} - \text{cholesterol in supernatant} \]

REFERENCE VALUES

The following uniform cut-off points have been established by the US National Cholesterol Education Program and have also been adopted in many other countries for the evaluation of coronary artery disease risk.

- Up to 100 mg/dL: 2.59 mmol/L
- 100-129 mg/dL: 2.58-3.34 mmol/L
- 130-159 mg/dL: 3.37-4.12 mmol/L
- 160-189 mg/dL: 4.14-5.09 mmol/L
- 190 mg/dL: 5.09 mmol/L

QUALITY CONTROL

It is recommended to use the Lipid Control Serum level I (cod. 18034) and II (cod. 18041) to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

METROLOGICAL CHARACTERISTICS

- Detection limit: 0.45 mg/dL = 0.01 mmol/L.
- Linearity limit: 1600 mg/dL = 26 mmol/L.
- Repeatability (within run):
  - Mean Concentration
  - CV
  - n
  - 120 mg/dL = 3.11 mmol/L: 1.6% 20
  - 200 mg/dL = 5.18 mmol/L: 1.4% 20

- Reproducibility (run to run):
  - Mean Concentration
  - CV
  - n
  - 120 mg/dL = 3.11 mmol/L: 2.8% 25
  - 200 mg/dL = 5.18 mmol/L: 1.5% 25

- Troponins: Results obtained with this reagent did not show systematic differences when compared with reference reagents (Note 4). Details of the comparison experiments are available on request.
- Interferences: Lipids (high density lipoprotein) does not interfere. Bilirubin (10 mg/dL) and hemoglobin (5 g/dL) may interfere. Other drugs and substances may interfere.

These metrological characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

DIAGNOSTIC CHARACTERISTICS

LDL is the main lipoprotein transporting cholesterol from liver to tissues.

Increased plasma LDL-cholesterol concentrations are positively correlated with the incidence of atherosclerotic diseases, basis of myocardial infarction and cerebrovascular accidents.

There are several disease states or environmental influences associated with increased levels of LDL-cholesterol: nephropathy, diabetes, obesity, some drugs and smoking.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

NOTES

1. Sample and Reagent volumes may be varied as long as the same ratio is maintained.

2. Supersaturation must be cleared. When supranatant is turbid or the pellet floats, add again 0.2 mL of Reagent, mix thoroughly and centrifugate. Multiply the obtained concentration by 1.5 (dilution).

3. These reagents may be used in several automatic analysers. Instruction for many of these are available on request.

4. Calibration with the provided aqueous standard may cause a matrix related bias, specially in some analysers. In these cases, it is recommended to calibrate using a serum based standard (Biochemistry Calibrator, cod. 18031 and 18041).

BIBLIOGRAPHY


