DXC 800 (CHOL) CHOLESTEROL

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☐ St. Clare Hospital Lakewood, WA	☐ Highline Medical Center Burien, WA	☐ PSC

PURPOSE

To provide instructions for the quantitative determination of Cholesterol on the DXC 800.

PRINCIPLE

CHOL reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and SYNCHRON® Systems Multi Calibrator, is intended for quantitative determination of Cholesterol concentration in human serum or plasma.

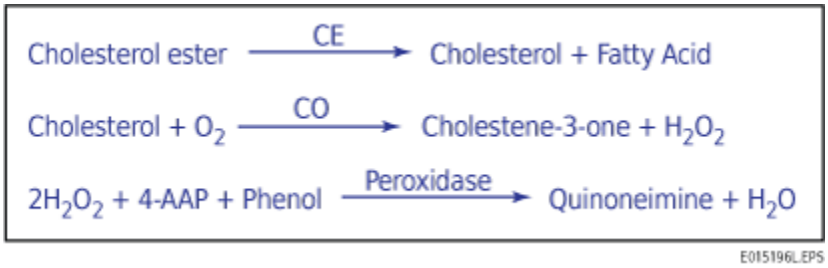
BACKGROUND

Clinical Significance

Cholesterol measurements are used in the diagnosis and treatment of atherosclerotic coronary artery disease. Cholesterol measurements are also used in the diagnosis of metabolic disorders involving lipids and lipoproteins. Total serum cholesterol concentrations depend on many factors including age, gender, diet, physical activity, liver disease, and other metabolic disorders.

Methodology

CHOL reagent is used to measure cholesterol concentration by a timed-endpoint method. In the reaction, cholesterol esterase (CE) hydrolyzes cholesterol esters to free cholesterol and fatty acids. Free cholesterol is oxidized to cholestene-3-one and hydrogen peroxide by cholesterol oxidase (CO). Peroxidase catalyzes the reaction of hydrogen peroxide with 4-aminoantipyrine (4-AAP) and phenol to produce a colored quinoneimine product.
The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 100 parts reagent. The system monitors the change in absorbance at 520 nanometers. This change in absorbance is directly proportional to the concentration of CHOL in the sample and is used by the System to calculate and express CHOL concentration.



RELATED DOCUMENTS

R-PO-CH-0810 Quality Control Program General Laboratory

R-PO-CH-0809	Quality Control Westgard Rules Statistics
R-PR-AD-0540	Specimen Rejection/Cancellation Protocol
J-F-CH-0820	DXC 800 Controls
J-F-CH-0826	DXC 800 Calibrators
J-F-CH-1940	DXC Analytical Measurement Range

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma are the preferred specimens. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood or urine are not recommended for use as a sample.

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.

2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.

Sample Type	Volume	Sample Stability
Plasma/Serum	0.5mL	• Separate serum from cells within 2 hours • Room Temp 8 hours • Refrigerated 48 hours • Frozen 3 months

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

Sample Volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

REAGENTS

Contents

Each kit contains the following items:
Two CHOL Reagent Cartridges (2 x 300 tests)

Volume per Test	
Sample Volume	3 µL
Ordac Sample Volume	2 µL

Total Reagent Volume	300 µL
Cartridge Volumes	A 290 µL B -- C 10 µL

Reactive Ingredients	
4-Aminoantipyrine	0.28 mmol/L
Phenol	8.06 mmol/L
Cholesterol esterase (Candida Cylindracea)	211 IU/L
Cholesterol oxidase (Brevibacterium Maris)	216 IU/L
Peroxidase (horseradish)	6667 IU/L

Also non-reactive chemicals necessary for optimal system performance.

Reagent Preparation

No preparation is required.

Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within acceptance criteria.

Reagent Storage and Stability

CHOL reagent when stored unopened at +2°C to +8°C will obtain the shelf-life indicated on the cartridge label. Once opened, the reagent is stable for 30 days at +2°C to +8°C unless the expiration date is exceeded. DO NOT FREEZE.

CALIBRATION

Calibrator Required

SYNCHRON® Systems Multi Calibrator

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

If unopened, the SYNCHRON® Systems Multi Calibrator should be stored at -15°C to -20°C until the expiration date printed on the calibrator bottle. Opened calibrators that are resealed and stored at +2°C to +8°C are stable for 20 days unless the expiration date is exceeded.

Calibration Information

1. The system must have valid calibration factors in memory before controls or patient samples can be run.

2. Under typical operating conditions the CHOL reagent cartridge must be calibrated every 14 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual for information on this feature.

3. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

4. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Traceability

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

See Related Documents J-F-CH0820 DXC 800 Controls

STEPS

1. If necessary, load the reagent onto the system.

2. After reagent load is completed, calibration may be required.

3. Program samples and controls for analysis.

4. After loading samples and controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. .For detailed testing procedures, refer to the UniCel DxC 600/800 System Instructions For Use (IFU) manual.

CALCULATIONS

SYNCHRON® System(s) perform all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

ANTICOAGULANT TEST RESULTS

If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Anticoagulant	Level Tested
Ammonium Heparin	29 Units/mL
Lithium Heparin	29 Units/mL
Sodium Heparin	29 Units/mL

The following anticoagulant was found to be incompatible with this method:

Incompatible Anticoagulants

Anticoagulant	Level Tested for In Vitro Interference	Plasma-Serum Bias
EDTA	3.0 mg/mL	≤-24.0
Sodium Citrate	6.6 mg/mL	≤-79.0
Potassium Oxalate/Sodium Fluoride	4.0 / 5.0 mg/mL	≤-60.0

PERFORMANCE CHARACTERISTICS

Reference Range

0-150 Years 0—199 mg/dL

Analytic Range

The SYNCHRON® System(s) method for the determination of this analyte provides the following analytical ranges:

Sample Type	Conventional Units
Serum or Plasma	5 – 750 mg/dL
Serum or Plasma (ORDAC)	600– 1000 mg/dL

Samples with concentrations exceeding the high end of the analytical range should be rerun with ORDAC enabled or diluted with saline and reanalyzed.

Reporting results outside of analytical range

Lower limit of detection	5mg/dL	Results below 5, report as <5mg/dl
Upper limit of detection	1000 mg/dL	Results >1000mg/dL, should be diluted with 0.9% saline, reanalyzed and dilution factor applied. The maximum allowable dilution is X2. Results >2000 are reported as >2000 mg/dL.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for CHOL determination is 5 mg/dL (0.13 mmol/L).

LIMITATIONS

None identified.

Interferences

The following substances were tested for interference with this methodology:

Substance	Source	Level Tested	Observed Effect

Substance	Source	Level Tested	Observed Effect
Hemoglobin	RBC hemolysate	(4+) 500 mg/dL INDEX of 10	No significant interference (within ± 10.0 mg/dL or 6%)
Bilirubin	Bovine (unconjugated)	30 mg/dL INDEX of 20	≤ - 25 mg/dL
			@ 400 mg/dL
Lipemia	Intralipid[h]	(4+) 400 mg/dL INDEX of 10	No significant interference (within ± 10.0 mg/dL or 6%)
Ascorbic Acid	NA[i]	3 mg/dL	No significant interference (within ± 10.0 mg/dL or 6%)
Albumin	Human	7.7 g/dL	≤ - 12 mg/dL
			@ 240 mg/dL
Urea	NA	500 mg/dL	No significant interference (within ± 10.0 mg/dL or 6%)

1. Samples or control materials which contain acetic acid, detergents, or surfactants may inhibit the enzymes in the reagent and should not be used.

2. Refer to References for other interferences caused by drugs, disease and preanalytical variables.

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

REFERENCES

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DOCUMENT APPROVAL **Purpose of Document / Reason for Change:**			
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