

# CHOLESTEROL FL

CT F100 CH	2 x 50 ml
CT F400 CH	4 x 100 ml
CT 100F CH	4 x 250 ml

## INTENDED USE

Reagent for quantitative in vitro determination of cholesterol in biological fluids.

## SUMMARY OF TEST

Although every living organism examined has been found to contain sterols, cholesterol is found almost exclusively in animals and humans, in which it is also the main sterol. Cholesterol is the initial starting point in many metabolic pathways. These include vitamin D synthesis, steroid hormone synthesis, and bile acid metabolism. Cholesterol is presented to the intestinal wall from three sources: the diet, bile and intestinal secretions, and cells.

## PRINCIPLE OF THE METHOD

All cholesterol esters present in plasma are hydrolyzed quantitatively into free cholesterol and fatty acids by cholesterol esterase. In the presence of oxygen, free cholesterol is then oxidized by cholesterol oxidase to cholesterol-4-ene-3-one and  $H_2O_2$ . The  $H_2O_2$  reacts with p-chlorophenol and 4-aminoantipyrine in the presence of peroxidase to form a quinoneimine dye. The intensity of color formed is proportional to the cholesterol concentration and can be measured photometrically between 480 and 520 nm.

## KIT COMPONENTS

**For in vitro diagnostic use only.**

The components of the kit are stable until expiration date on the label.

Keep away from direct light sources.

**CHOL R1 F100: 2 x 50 ml (liquid) blue cap**  
**F400: 4 x 100 ml (liquid) blue cap**  
**100F: 4 x 250 ml (liquid) blue cap**

Composition: Good's buffer pH 7.20, sodium cholate 8 mM, CHE  $\geq$  400 U/l, CHOD  $\geq$  200 U/l, POD  $\geq$  500 U/l, 4-AAP 0.6 mM, 4-chlorophenol 2 mM.

**Standard: cholesterol solution 200 mg/dl - 5 ml**

Store all components at 2-8°C.

## MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micro-pipettes. Glass or high quality polystyrene cuvettes. Saline solution.

## PRECAUTIONS

**CHOL R1: Warning.** Causes serious eye irritation (H319). Causes skin irritation (H315). Wear protective gloves. Eye protection (P280). IF ON SKIN: Wash with plenty of water (P302+P352). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). If eye irritation persists: get medical advice (P337+P313).

**Standard:** It is not classified as hazardous.

## REAGENT PREPARATION

Use reagent ready to use.

Stability: up to expiration date on labels at 2-8°C.

Stability since first opening of vials: preferably within 60 days at 2-8°C.

## SPECIMEN

Serum, plasma EDTA.

Sample is stable 3 days at 2-8°C and 1 month at -20°C.

## TEST PROCEDURE

Wavelength:	510 nm (allowed 480 ÷ 520 nm)		
Lightpath:	1 cm		
Temperature:	37°C		
dispense:	blank	standard	sample
reagent	1 ml	1 ml	1 ml
water	10 $\mu$ l	-	-
standard	-	10 $\mu$ l	-
sample	-	-	10 $\mu$ l

Mix, incubate at 37°C for 5 minutes.  
Read absorbances of standard (As) and samples (Ax) against reagent blank.

## RESULTS CALCULATION

serum/plasma sample:

cholesterol mg/dl =  $A_x/A_s \times 200$  (standard value)

## EXPECTED VALUES

desirable: 140 - 200 mg/dl  
borderline/high risk: 200 - 240 mg/dl  
high risk:  $> 240$  mg/dl

Each laboratory should establish appropriate reference intervals related to its population.

## QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:

### QUANTINORM CHEMA

with normal or close to normal control values

### QUANTIPATH CHEMA

with pathological control values.

If required, a multiparametric, human based calibrator is available:

### AUTOCAL H

Please contact Customer Care for further information.

## TEST PERFORMANCE

### Linearity

the method is linear up to 700 mg/dl.

If the limit value is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

### Sensitivity/limit of detection (LOD)

the limit of detection is 1 mg/dl.

### Interferences

no interference was observed by the presence of:

hemoglobin  $\leq$  500 mg/dl  
bilirubin  $\leq$  15 mg/dl  
lipids  $\leq$  850 mg/dl

### Precision

intra-assay (n=10)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	101.50	1.84	1.80
sample 2	176.20	2.74	1.60

inter-assay (n=20)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	100.99	2.11	2.10
sample 2	176.51	2.23	1.30

### Methods comparison

a comparison between Chema and a commercially available product gave the following results:

Cholesterol FL Chema = x  
Cholesterol competitor = y  
n = 100

$y = 0.979x - 1.71$  mg/dl  $r^2 = 0.995$

## WASTE DISPOSAL

This product is made to be used in professional laboratories.

P501: Dispose of contents according to national/international regulations.








## REFERENCES

Trinder P., - J. Clin. Path. 22, 158 (1969);  
Allain C.C., Poon L.S., Chan C.S., Richmond W., Fu P.C., - Clin. Chem. 20,470 (1974).  
National Cholesterol Education Program (NCEP) recommended values for cholesterol  
Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).

## MANUFACTURER

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## SYMBOLS

	in vitro diagnostic medical device
	batch code
	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use