ELITechGroup
CLINICAL SYSTEMS

ELITech Clinical Systems
Selectra Pro Series Analyzers

CHOLESTEROL HDL SL 2G

***In vitro* diagnostic reagent, for professional use only**

☛References :
HDLL-0230 4 x 28 mL

Kit composition :
R1 12 x 20 mL + **R2** 4 x 7 mL

☛CAUTION: Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner (Rx ONLY)

INTENDED USE
ELITech Clinical Systems CHOLESTEROL HDL SL 2G is intended for the quantitative in vitro diagnostic determination of High Density Lipoprotein (HDL) Cholesterol in human serum and plasma on ELITech Clinical Systems Selectra Pro Series Analyzers. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
It is not intended for use in Point of Care settings.*

CLINICAL SIGNIFICANCE [1-4]
Cholesterol is a lipidic molecule, insoluble in aqueous medium such as plasma, in which it circulates in form of pseudo-emulsion : association of lipids and proteins constituting lipoproteins. These lipoproteins vary quantitatively and qualitatively in their lipidic and proteic composition, inducing structural and functional differences to them. The most used classification is that which is based on their difference in density. This explains the name of High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL), Very Low Density Lipoprotein (VLDL) and the existence of many intermediate fractions which correspond to all the stages of the lipidic metabolism. HDL contain approximately 50 % lipids including 20 % cholesterol. The HDL molecule plays an integral role in removing cellular cholesterol and thus in cellular purification. Many epidemiologic studies confirm the anti-atherogen fonction of this fraction leading to the concept of «good cholesterol». Consequently HDL represents an element of evaluation of the atherogenesis risk when there is an imbalance of the ratios cholesterol total/cholesterol HDL or cholesterol LDL/cholesterol HDL.

METHOD
Enzymatic. Colorimetric. End point. Accelerator selective detergent.

PRINCIPLE
1st step :
When a sample is mixed with reagent R1 containing a selective accelerator, cholesterol of non-HDL lipoproteins is subject to enzymatic reactions to be eliminated:

$$\text{LDL, VLDL, Chylomicron} \xrightarrow{\textit{Accelerator + CO + DSBmT + POD}} \text{Non-reactive LDL, VLDL, Chylomicron}$$

2nd step :
When reagent R2 is added, HDL is solubilized by a specific detergent, then HDL cholesterol is measured by enzymatic reactions:

$$\text{HDL} \xrightarrow{\textit{HDL specific detergent}} \text{Solubilized HDL}$$

$$\text{HDL Cholesterol} + O_2 \xrightarrow{\textit{CHE + CO}} \text{Cholest-4-en-3-one} + H_2O_2$$

$$H_2O_2 + \text{4-AA} + \text{DSBmT} \xrightarrow{\textit{Peroxidase}} \text{Colored compound}$$

REAGENT COMPOSITION
Reagent 1 : R1
Good's buffer, pH 6.0

Cholesterol oxidase (CO) (bacterial)	<	1000	U/L
Peroxidase (POD) (Horseradish)	<	1300	ppg U/L
Ascorbate oxidase (vegetal)	<	3000	U/L
N,N-bis(4-sulphobutyl)-*m*-toluidine-disodium (DSBmT)	<	1	mmol/L
Accelerator	<	1	mmol/L
Preservative	<	0.06	%

Reagent 2 : R2
Good's buffer, pH 6.0

Cholesterol esterase (CHE) (bacterial)	<	1500	U/L
4-Amino-Antipyrine (4-AA)	<	1	mmol/L
Detergent	<	2	%
Preservative	<	0.06	%

MATERIAL REQUIRED BUT NOT PROVIDED

- HDLL-0041	Cholesterol HDL 2G Calibrator	4 x 1 mL
- CONT-0080	ELITROL I	10 x 5 mL
- CONT-0180	ELITROL II	10 x 5 mL

- General Laboratory Equipment.

PRECAUTIONS AND WARNING
- This reagent is for professional *in vitro* diagnostic use only.
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contamination.
- Do not freeze reagents.
- For more information, Safety Data Sheet (SDS) is available on request for the professional user.

WASTE MANAGEMENT
Disposal of all waste material should be in accordance with local, state and Federal regulatory requirements.

STABILITY OF REAGENTS
Store at 2-8 °C and protect from light.
Reagents are stable until the expiry date stated on the label.
On board stability: Refer to § PERFORMANCE DATA.

PREPARATION
Reagents are ready for use.

REAGENT DETERIORATION
The reagent R1 should be clear. The reagent R2 may present a slightly hazy appearance. This has no effect on the performances of the product. Cloudiness would indicate deterioration for reagent R1.

☛SAMPLES [1,3]
Specimen
- Serum or plasma in lithium heparin drawn from the fasting patient (≥ 12 hours) are the required specimens. Separate from cells within 2 hours. To reduce biological variability, collection of samples should follow standardized conditions as recommended by NCEP.
- Venipuncture should be performed prior to the administration of drugs. Of particular note, venipuncture performed during an acetaminophen overdose situation, when N-acetyl-p-benzoquinone imine (NAPQI) an atypical metabolic breakdown product of acetaminophen, may be present, may lead to erroneously low HDL Cholesterol results.
- Venipuncture performed during or immediately after administration of N-acetylcysteine (NAC), a drug used to treat acetaminophen overdose, or Metamizole may lead to erroneously low HDL cholesterol results.

Storage
Store samples at 2-8 °C before analysis. Specimens are stable 7 days at 2-8 °C. For longer storage, freeze them at -70 °C or lower (frozen once).

☛REFERENCE VALUES [4]
The NCEP (American National Cholesterol Education Program) has established the following classification for HDL cholesterol levels according to the risk of developing coronary heart disease:

Risk Classification	Level (mg/dL)	Level (mmol/L)
High risk	< 40	< 1.03
Low risk	≥ 60	≥ 1.55

Note : *It is recommended that each laboratory establishes and maintains its own reference values. The data given here are only for informationn.*

Conversion factor: mg/dL x 0.0259 = mmol/L

☛PROCEDURE
- See application included in the barcode indicated at the end of the insert.

- Triglycerides SL reagent as well as some other reagents containing peroxidase can be contaminated by Cholesterol HDL SL 2G reagent.
In order to avoid contamination on Selectra ProM, program incompatibilities as follows:

Software	Menu	Parameter
TouchPro	Probe incompatibilities	Link / Cholesterol HDL SL 2G –Acid Solution
Other	Needle incompatibility	Cholesterol HDL SL 2G <<HCl

For ProS, repeat any absurd results after programming a needle wash.

CALIBRATION
ELITech Clinical Systems Cholesterol HDL 2G Calibrator should be used for calibration. Its value is traceable to the reference method recommended by the CDC (Centers for Disease Control and Prevention).
Calibration frequency: refer to § PERFORMANCE DATA.

QUALITY CONTROL
To ensure adequate quality, control sera such as ELITROL I and ELITROL II should be used. These controls should be assayed together with patient samples, at least once a day and after each calibration.The control frequency should be adapted to Quality Control procedures of each laboratory and the regulatory requirements. Results should be within the defined ranges. If values fall outside of the defined ranges, each laboratory should take corrective measures. Quality control materials should be used in accordance with local, state, and/or federal guidelines.

CERTIFICATION
The reagent system has not been tested by the CRMLN (Cholesterol Reference Method Laboratory Network).

PERFORMANCE DATA at 37 °C
A) On ELITech Clinical Systems Selectra ProM Analyzers

- Measuring range
Determined according to CLSI[5] EP6-A protocol, the measuring range is from 5 to 105 mg/dL (0.13-2.72 mmol/L).

- Limit of Detection (LoD) and Limit of Quantification (LoQ)
Determined according to CLSI[6] EP17-A protocol.
LoD = 1.2 mg/dL (0.03 mmol/L)
LoQ = 5.0 mg/dL (0.13 mmol/L)

- Precision
Determined according to CLSI[7] EP5-A2 protocol.

		Mean		Within-run	Total
	N	mg/dL	mmol/L	CV (%)	
Low level	80	28	0.72	1.6	5.5
Medium level	80	54	1.40	1.7	3.9
High level	80	80	2.07	1.0	3.5

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* : US FDA only
☛: Modification from previous version

(03/2016)
FTNA-HDLL-v6

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HDLL-0230 *4 x 28 mL*

Kit composition :
R1 *12 x 20 mL* + ***R2*** *4 x 7 mL*

- Correlation

A comparative study has been performed between an ELITech Clinical Systems Selectra ProM Analyzer and another FDA-Approved system equipment (equivalent method) on 90 human serum samples according to CLSI[8] EP9-A2 protocol. The sample concentrations ranged from 6 to 102 mg/dL (0.16 to 2.64 mmol/L).
The parameters of linear regression are as follows:
Correlation coefficient: (r) = 0.999
Linear regression: y = 0.998 x + 0.1 mg/dL

☛- Limitations / Interferences

- At least two measurements of cholesterol HDL should be made on separate occasions before any medical decision[9].

- Do not report results outside of the usable range.

- Studies have been performed to determine the level of interference from different compounds according to CLSI[10] EP7-A2 protocol and SFBC recommendations[11]. Recovery within ± 10% of initial value at HDL Cholesterol concentration of 31 mg/dL and 54 mg/dL.

Conjugated Bilirubin : No significant interference up to 29.5 mg/dL (504 µmol/L).
Unconjugated Bilirubin : No significant interference up to 30 mg/dL (513 µmol/L).
Turbidity : No significant interference up 614 mg/dL (6.94 mmol/L) triglycerides equivalent.
Hemoglobin : No significant interference up to 500 mg/dL (5 g/L).
Ascorbic acid : No significant interference up to 20.0 mg/dL (1136 µmol/L)

- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macro-globulinemia) can cause unreliable results.[12]

- Results may be falsely low when the sample is taken while levels of NAC, NAPQI (a metabolite of acetaminophen (paracetamol)) or Metamizole are significant.

- Other compounds may interfere.[13,14]

- The results of this assay should only be interpreted in conjunction with other diagnostic test results, clinical findings and the patient's medical history.

- On board stability/Calibration frequency

On Board Stability : 28 days
Calibration frequency (refrigerated position):
Recalibrate when reagent lots change, when quality control results - fall outside the established range, and after a maintenance operation.

B) On ELITech Clinical Systems Selectra ProS Analyzers

- Measuring range

Determined according to CLSI[5] EP6-A protocol, the measuring range is from 5 to 105 mg/dL (0.13-2.72 mmol/L).

- Limit of Detection (LoD) and Limit of Quantification (LoQ)

Determined according to CLSI[6] EP17-A protocol.
LoD = 0.4 mg/dL (0.01 mmol/L)
LoQ = 5.0 mg/dL (0.13 mmol/L)

- Precision

Determined according to CLSI[7] EP5-A2 protocol.

		Mean		Within-run	Total
	N	mg/dL	mmol/L	CV (%)	
Low level	80	28	0.72	1.4	4.2
Medium level	80	50	1.29	0.9	2.5
High level	80	83	2.15	0.9	2.2

- Correlation

A comparative study has been performed between an ELITech Clinical Systems Selectra ProS Analyzer and another FDA-Approved system equipment (equivalent method) on 88 human serum samples according to CLSI[8] EP9-A2 protocol. The sample concentrations ranged from 6 to 102 mg/dL (0.16 to 2.64 mmol/L).
The parameters of linear regression are as follows:
Correlation coefficient: (r) = 0.998
Linear regression: y = 1.008 x - 0.6 mg/dL (0.02 mmol/L)

☛- Limitations / Interferences

- At least two measurements of cholesterol HDL should be made on separate occasions before any medical decision[9].

- Do not report results outside of the usable range.

- Studies have been performed to determine the level of interference from different compounds according to CLSI[10] EP7-A2 protocol and SFBC recommendations[11]. Recovery within ± 10% of initial value at HDL Cholesterol concentration of 31 mg/dL and 54 mg/dL.

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☛BIBLIOGRAPHY

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☛SYMBOLS

IVD *In vitro* diagnostic medical device	Temperature limitation
Consult instruction for use	LOT Batch code
Manufacturer	Use by
REF Catalogue number	CE European Conformity

☛ **IMPORTANT NOTE/see § PROCEDURE:**
- Contamination risk

HDL Cholesterol 0
340 FTNA-HDLL

☛: Modification from previous version

(03/2016)
FTNA-HDLL-v6

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