HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

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| **Department:** | Laboratory and Blood Bank ( Chemistry ) | | |
| **Document:** | Internal Policy and Procedure | | |
| **Title:** | Analysis of Low-Density Lipoproteins Level | | |
| **Applies To:** | All Laboratory Staff | | |
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## 1. PURPOSE:

1.1 The purpose of this policy & procedure is to provide all information related to the analysis of LDL level in blood (serum/plasma) on DimensionEXL200 ,SynchronDXC700 and Atelica CI.

## 2. DEFINITONS:

2.1 The Low-Density Lipoproteins (LDLs) are derived by the action of various lipolytic enzymes and are synthesized in the liver.

## 3. POLICY:

3.1 It is an in-vitro test for the quantitative determination of low-density lipoprotein cholesterol (LDL-C) concentration in human serum and plasma on DimensionEXL200 ,SynchronDXC700 and Atelica CI. machines.

3.2 The Low-Density Lipoproteins (LDLs) are synthesized in the liver. The elimination of LDL from plasma takes place mainly by liver parenchymal cells via specific LDL receptor. The LDL-C plays a key role in causing and influencing the progression of atherosclerosis and coronary sclerosis. It increases in atherosclerosis, coronary sclerosis, DM and renal diseases.

## 4. PROCEDURE:

4.1 **Specimen:**

- 4.1.1 Type:
  - 4.1.1.1 Serum, or plasma.
- 4.1.2 Tube Type:
  - 4.1.2.1 Gel tube, Plain tube; Li-Heparin.
- 4.1.3 Amount Required:
  - 4.1.3.1 2.0 to 3.0 ml.
- 4.1.4 Delivery Arrangements:
  - 4.1.4.1 Sample to be delivered to the lab as soon as possible. If the sample is serum should be ensuring complete clot formation before centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time. If the specimen is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.
- 4.1.5 Temperature Restrictions:
  - 4.1.5.1 At room temperature.
- 4.1.6 Unacceptable Specimen:
  - 4.1.6.1 See sample rejection criteria policy.
- 4.1.7 Specimen Retention:
  - 4.1.7.1 Period of retention: up to one week after separation of the sample.
  - 4.1.7.2 Storage condition: store at 2-8°C.

4.1.8 Safety Precaution:

4.1.8.1 Treat all samples material as infectious and handled in accordance with the OHSA standard on blood borne pathogens.

4.2 **Principle:**

4.2.1

detergent cholesterol esterase

LDL-cholesterol ester + H ----------cholesterol + free fatty acid (selective micellary solubilisation).

Cholesterol esters are broken down quantitatively into free cholesterol and fatty acids by cholesterol esterase.

4.2.2

cholesterol oxidase

LDL-cholesterol + 02----------04-cholestenone + H202

In the presence of oxygen, cholesterol is oxidized by cholesterol oxidase to 04-cholestenone and hydrogen peroxide.

4.2.3

peroxidase

2 H202 + 4-aminoantipyrine + HSDAa + H+ + H2----------purple blue pigment + 5 H2O

In the presence of peroxidase, the hydrogen peroxide generated reacts with 4-aminoantipyrine and HSDA to form a purple-blue dye. The color intensity of this dye is directly proportional to the cholesterol concentration and is measured photometrically at 540-700 nm.

4.3 **Method:**

4.3.1 See policy of loading sample on machine (Ref: Operative Manuals' of DimensionEXL200 ,SynchronDXC700 and Atelica CI.

4.4 **Calculation:**

4.4.1 Instrument system automatically calculates the Analytic activity and gives results in the form of printout.

4.5 **Format:**

4.5.1 Numeric

4.6 **Status:**

4.6.1 Stat and Routine

4.7 **Reference ranges:**

4.7.1 Serum/plasma 0-3.879 mmol/L

4.8 **Dilution information:**

4.8.1 Specimens with values exceeding the linearity range are flagged and may be diluted with automatic dilution either automated or manual dilution. Manual Dilution should be performed as follows:

4.8.1.1 Use saline (0.85% to 0.90%) to dilute the sample

4.8.1.2 The operator must enter the dilution factor in the patient order screen. The system dilution factor to automatically correct the concentration by multiplying the result by factor.

4.8.1.3 If the operator does not enter the dilution factor, the result must be multiplied appropriate dilution factor before reporting the result .

4.8.1.4 If a diluted sample result generates a Linear Low (LL) result error code. do result. Prepare an appropriate dilution/concentration and rerun.

4.9 **Linearity:**

4.9.1 LDL is leaner up to 7.758 mmol/L

4.10 **Limit of Detection:**

4.10.1 The Limit of Detection is from 0.1293 mmol/L

## 5. MATERIALS AND EQUIPMENT:

### 5.1 Reagent:

5.1.1 ALDL flex Cat. No. DF131 contains 6 wells with the following ingredients:

| Reactive Ingredients |
|---|
| Liquid (1-3 wells) |
| MES Buffer |
| Detergent 1 |
| Cholesterol Esterase |
| Cholesterol Oxidase |
| Peroxidase 4-aminoantipyrine (4-AA) |
| Ascorbic acid oxidase Preservative |
| Liquid (4-6 well) |
| MES Buffer |
| Detergent 2 |
| N,N-bis(4-sulfobutyl)-m-toluidine, disodium salt |

5.1.1.1. Reagent Preparation:

5.1.1.1.1 mixing and diluting are automatically performed by the Dimension system

5.1.1.1.2 Estimated test per cassette, 30 tests

5.1.1.1.3 Analytical Range: Serum/plasma 5 — 300 mg/dL (0.13 — 7.8 mmol/L)

5.1.1.1.4 Refer to Bachman Coulter kit leaflet

5.1.2 Regents retention:

5.1.2.1 The unopened reagents are stable until the expiration date when stored at 2-8U. Reagent stability is 30 days if the reagent is unopened and for 5 days if the reagent is opened 1-6 wells.

### 5.2 Calibration:

5.2.1 Calibration is stable approximately 30 days and required with each change in reagent lot number. Verify calibration curve with at least two levels of controls according to the established Quality Control requirements for your laboratory. Calibration must be done when:

5.2.1.1 A complete change of reagents that affects the range used to report patient results or QC value

5.2.1.2 A reagent kit with new lot number is used

5.2.1.3 A new assay file that requires a calibration is installed

5.2.1.4 QC fails to meet the established criteria

5.2.1.5 After major maintenance or service

5.2.1.6 When recommended by the manufacturer

5.2.1.7 Documentation accompanying a new version of an existing file states calibration is required

5.2.1.8 At least every 6 months

5.2.2 Calibrator retention:

5.2.2.1 At 2-8°C for 24 h. Instability or deterioration should be suspected if there are visible signs of leakage, extreme turbidity microbial growth or if calibration does not meet the appropriate package insert and/or instrument operation manual criteria.

5.2.3 Calibration Procedure:

5.2.3.1 Verify that the correct calibrator values have been entered into the calibration file. For details refer to Operator Guide of DimensionEXL200 ,SynchronDXC700 and Atelica CI.

5.2.3.2 Allow calibrator to come to room temperature.

5.2.3.3 Mix bottle 10 times by inversion.

5.2.3.4 Open bottle, place a minimum of 300 ul of each level in separate sample cup, and place on the assigned positions.

5.2.3.5 Cap bottle tightly and store at 2-8°C. Immediately after use.

5.2.3.6 Perform calibration as indicated in Operator Guide of DimensionEXL200 ,SynchronDXC700 and Atelica CI.

5.2.4 Calibration Expected Values:

5.2.4.1 Refer to ALDL calibrator for DimensionEXL200 ,SynchronDXC700 and Atelica CI.

5.3 **Quality control:**

5.3.1 Normal and pathological control one time in 24 hours. If more frequent control monitoring is required, the established quality control procedures is followed If quality control results do not fall within an acceptable range defined by laboratory, patient be affected and corrective action should be taken

5.3.2 Quality Control retention:

5.3.2.1 Unopened control vial is stable up to expiry date printed on the label when stored at cold room.

5.3.2.2 Opened control vial for all analytics will be stable for 7 days except Bilirubin (Direct) for 4 days at 2 — 8 °C, All analytics will be stable for 30 days at -10 to -20 °C.

5.3.2.3 Instability or deterioration should be suspected if there are visible signs of leakage, extreme microbial growth or if calibration does not meet the appropriate package insert and/or instrument operation manual criteria.

5.3.3 QC Procedure:

5.3.3.1 Verify that the correct QC values have been entered into the QC file. For details refer to Operator Guide of DimensionEXL200 ,SynchronDXC700 and Atelica CI.

5.3.3.2 Allow QC to come to room temperature.

5.3.3.3 Gently remove the stopper to avoid loss of the lyophilized pellet and add exactly 5.0 ml distilled or de-ionized water.

5.3.3.4 Leave to stand for 20 minutes. Mix bottle several times by inversion to allow homogeneity.

5.3.3.5 Gently invert just prior to use. Avoid foaming.

5.3.3.6 Open bottle, place a minimum of 1000 ul of each level in separate sample cup, and place on the assigned positions.

5.3.3.7 Cap bottle tightly and store at 2-8°C, immediately after use .

5.3.3.8 Perform QC as indicated in Operator Guide of Dimension.

5.3.4 QC Expected Values: Refer to the Bio-Rad Lyphochek assayed chemistry controls value sheet for DimensionEXL200 ,SynchronDXC700 and Atelica CI.

## 6. RESPONSIBILITIES:

6.1 Chemistry shift on charge is responsible for, running calibration and control and samples of LDL

6.2 Chemistry staff are responsible for running LDL samples all over the day

## 7. APPENDICES:

7.1 N/A

## 8. REFERENCES:

8.1 Tietz Text Book of clinical chemistry and molecular diagnostics 4th Edition,2006

8.2 Company Leaflets of reagents

## 9. APPROVALS:

| | Name | Title | Signature | Date |
|---|---|---|---|---|
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