HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Chemistry)		
Document:	Internal Policy and Procedure		
Title:	Analysis of HDL Cholesterol level		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

1.1 The purpose of this policy and procedure is to provide all information related to the analysis of HDL Cholesterol level in blood (serum/plasma).

2. DEFINITONS:

2.1 N/A

3. POLICY:

3.1 This policy provides instructions for performing the quantitative determination of HDL Cholesterol in human serum or plasma on DimensionEXL200 ,Synchron DXC700 and Atelica CI machines

3.2 It is a test used to assess the value of HDL Cholesterol in patient blood.

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:
- 4.1.5 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.
- 4.1.6 Temperature Restrictions:
  - 4.1.6.1 At room temperature
- 4.1.7 Unacceptable Specimen:
  - 4.1.7.1 See sample rejection criteria policy
- 4.1.8 Specimen Retention:
  - 4.1.8.1 Period of retention: up to one week after separation of the sample
  - 4.1.8.2 Storage condition: store at 2-8 t
- 4.1.9 Safety Precaution:
  - 4.1.9.1 Treat all samples material as infectious and handled in accordance with the OHSA standard on blood borne pathogens.

4.2 **Principle:**

- 4.2.1 Refer to kit insert sheet

4.3 **Method:**

4.3.1 See policy of loading sample on machine (Ref: Operative Manuals' of DimensionEXL200 ,Synchron DXC700 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 1.036-1.554 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 HDL cholesterol is linear up to3.885 mmol/L

4.10 **Limit of Detection:**

4.10.1 The Limit of Detection is 0.259 mmol/L

5. MATERIALS AND EQUIPMENT:

5.1 **Reagents:**

5.1.1 Use HDL cassette Cat. No. DF48B contains 6 wells with the following ingredients:

Reactive Ingredients	Ingredients Concentration
Liquid (1-3 wells)	
HEPES buffer	10.07 mmol/L
Ethanesulfonic acid	96.95 mmol/L
Dextran sulfate	1.5 g/L
3,5-dimethoxyaniline	0.96 mmol/L
Ascorbate oxidase	>50 ukat/L
peroxidase	>16.7 ukat/L
Liquid (4 wells)	
HEPES buffer	10.07 mmol/L
PEG-cholesterol esterase	>3.33 ukat/L
PEG-cholesterol oxidase	>127ukat/L
Peroxidase	>333 ukat/L
4-amino-antipyrine	2.46 mmol/L
Liquid (5-6 wells)	
NaOH	1.00 M

5.1.2 Reagent Preparation

5.1.2.1 Mixing and diluting are automatically performed by the Dimension system.

5.1.2.2 Estimated test per flex, 30 tests

5.1.2.3 Analytical Range: Serum/plasma 0.0778-3.885 mmol/L

5.1.3 Regents retention:

5.1.3.1 The unopened reagents are stable until the expiration date when stored at 2-8C. Reagent stability is 30 days if the reagent is unopened and for 5 days if the reagent is opened well.

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.

5.2.2 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 ,Synchron DXC700 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 the 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 the bottle tightly and store at 2-8°C. Immediately after use.

5.2.3.6 Perform calibration as indicated in Operator Guide of DimensionEXL200 ,Synchron DXC700 and Atelica CI

5.2.4 Calibration Expected Values:

5.2.4.1 Refer to CHEM I calibrator for Dimension

5.2.4.2 Refer to DimensionEXL200 ,Synchron DXC700 and Atelica CI calibrator leaflet

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 analytes will be stable for 7 days except Bilirubin (Direct) for 4 days at 2 — 8 °C, All analytes 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 Dimension.

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 DimensionEXL200 and SynchronDXC600

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5.3.4 QC Expected Values:

5.3.4.1 Refer to the Bio-Rad Lyphochek assayed chemistry controls value sheet for Analysis of DimensionEXL200 ,Synchron DXC700 and Atelica CI.

6. RESPONSIBILITIES:

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

6.2 Chemistry staff are responsible for running HDL 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:

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