HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Chemistry)		
Document:	Internal Policy and Procedure		
Title:	Analysis of Triglycerides 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 triglyceride level in blood (serum/plasma) on DimensionEXL200 , SynchronDXC600 and Atelica machines .

2. DEFINITONS:

2.1 Triglycerides are esters of the trihydric alcohol glycerol with 3 long-chain fatty acids

3. POLICY:

3.1 This policy provides instructions for performing the quantitative determination of triglyceride in human serum or plasma on Dimension machines.

3.2 Triglycerides are esters of the trihydric alcohol glycerol with 3 long-chain fatty acids. They are partly synthesized in the liver and partly ingested in food. The determination of triglycerides is utilized in the diagnosis and treatment of patients having diabetes mellitus, nephrosis, liver obstruction, lipid metabolism disorders and numerous other endocrine diseases.

4. PROCEDURE:

4.1 **Specimen:**

4.1.1 Type:

4.1.1.1 Serum, or plasma

4.1.2 Tube Type: 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 ^{0}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:** Enzymatic colorimetric test.

Triglycerides + 3 H2O ----- LPL ------ glycerol + 3 RCOOH
Glycerol + ATP ----- GK------MG2------ glycerol-3-phosphate + ADP
Glycerol-3-phosphate + O2 ---------GPO------ dihydroxyacetone phosphate + H202

4.3 **Method:**

4.3.1 See policy of loading sample on machine (Ref: Operative Manuals' of Dimension ExL200 and Synchron DXC600 and Atelica machines.

4.4 **Calculation:**

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

4.5 **Format:** Numeric

4.6 **Status:** Stat and Routine

4.7 **Reference ranges:**

4.7.1 Serum/plasma 0.7758 - 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 TG is linear up to 25.86 mmol/L

4.10 **Limit of Detection:**

4.10.1 The Limit of Detection is 0.3879mmol/L

5. MATERIALS AND EQUIPMENT:

5.1 **REAGENTS:**

5.1.1 Refer to reagent leaflet of TG on DIMENSION and SYNCHRON and Atelica kits.

5.1.2 Reagent retention: The unopened reagents are stable until the expiration date when stored at 2-8°C. Reagent stability is 30 days if the reagent is unopened and for 10 days if the reagent is opened 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 ^{0}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 and Atelica, Machines

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 ,SynchronDXC600 and Atelica machines

5.2.4 Calibration Expected Values:

5.2.4.1 Refer to CHEM II calibrator for Dimension and Synchron and Atelica calibration

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 DimensionEXL200 and SynchronDXC600 and Atelica machines.

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 and Atellica machines.

5.3.4 QC Expected Values:

5.3.4.1 Refer to the Bio-Rad Lyphochek assayed chemistry controls value sheet for Dimension, Synchron and Atellica.

6. RESPONSIBILITIES:

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

6.2 Laboratory staff are responsible for running TG 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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