HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Chemistry)		
Document:	Internal Policy and Procedure		
Title:	Analysis of Lactic Acid 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 lactic acid (LA) level in blood (serum/plasma) on DimensionEXL200 ,Synchron DXC700 and Atelica CI machines.

2. DEFINITONS:

2.1 N/A

3. POLICY:

3.1 This policy provides instructions for performing the quantitative determination of lactic acid in human plasma on Dimension machines.

3.2 A lactic acid test is a blood test that measures the level of lactic acid made in the body. Most of it is made by muscle tissue and red blood cells. When the oxygen level in the body is normal, carbohydrate breaks down into water and carbon dioxide. When the oxygen level is low, carbohydrate breaks down for energy and makes lactic acid.

4. PROCEDURE:

4.1 **Specimen:**

- 4.1.1 Type:
  - 4.1.1.1 Plasma
- 4.1.2 Tube Type:
  - 4.1.2.1 sodium fluoride/potassium oxalate
- 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 immediately, separated from cells within 15 minutes.
- 4.1.5 Temperature Restrictions:
  - 4.1.5.1 Immediate transfer with ice.
- 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 24 hours after separation of the sample.
  - 4.1.7.2 Storage condition: store at 2-8 t for 24 hours or freeze it for up to 1 month.
- 4.1.8 Safety Precaution:
  - 4.1.8.1 Treat all samples as potentially infectious and handle in accordance with the OHSA standard on blood borne pathogens.

4.2 **Principle:**

4.2.1 Review the leaflet of LA od DimensionEXL200 ,Synchron DXC700 and Atelica CI.

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 print out.

4.5 **Format:**

4.5.1 Numeric

4.6 **References range:**

4.6.1 Venous plasma:0.4-2.0 mmol/L

4.6.2 Many define high as>4 mmol/L

4.6.3 CSF level:0.6-2.2 mmol/L

4.7 **Dilution Information:**

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

4.7.1.1 Use saline (0.85% to 0.90%) to dilute the sample.

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

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

4.7.1.4 If a diluted sample result generates a Linear Low (LL) result error code, do not report the result. Prepare an appropriate dilution/concentration and rerun.

4.8 **Test limitation:**

4.8.1 Recognizing:

4.8.1.1 Haemolysed sample

4.8.1.2 Lipemia: because of absorbance flagging > 600 mg/dl

4.8.1.3 Icterus: bilirubin > 80 mg/di

4.8.2 Avoiding Error:

4.8.2.1 Following acceptance criteria of the sample

4.8.2.2 By following the maintenance protocol. Daily, weekly, month

4.8.2.3 Run control before starting the tests

4.8.3 Error Correction:

4.8.3.1 Look for a fibrin clot or air bubbles.

4.8.3.2 Repeat the sample from the original tube.

4.8.3.3 Ask for another sample

5. MATERIALS AND EQUIPMENT:

5.1 Reagent:

5.1.1 Refer to reagent leaflet for DimensionEXL200 ,Synchron DXC700 and Atelica CI

5.1.2 Regents retention:

5.1.2.1 The unopened reagents are stable until the expiration date when stored at 2-8^0 C. Reagent stability is 30 days if the reagent is unopened and for 3 days if the reagent is in use.

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.

5.2.2 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

5.2.3 Calibrator retention:
5.2.3.1 2 — 8^0 C for 8 hours. 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.

5.2.4 Calibration Procedure:
5.2.4.1 Refer to CHEM I calibrator for DimensionEXL200 ,Synchron DXC700 and Atelica CI operator

5.2.5 Calibration Expected Values:
5.2.5.1 Refer to CHEM I calibrator for DimensionEXL200 ,Synchron DXC700 and Atelica CI operator

5.3 **Quality control:**

5.3.1 Run normal and pathological control once per day.

5.3.2 If more frequent control monitoring is required, follow the established quality control procedures your laboratory.

5.3.3 If quality control results do not fall within an acceptable range defined by your laboratory, may be affected and corrective action should be taken.

5.3.4 Quality Control retention:
5.3.4.1 Unopened control vial is stable up to expiry date printed on the label when stored at cold room.
5.3.4.2 Opened control vial is stable for: After reconstituting and tightly capped at 2 — 8 °C All analytes will be stable for 7 days except Bilirubin (Direct) for 4 days

5.3.5 QC Procedure:
5.3.5.1 Verify that the correct QC values have been entered into the QC file. For details refer to Operator Guide of Dimension.
5.3.5.2 Allow QC to come to room temperature.
5.3.5.3 Gently remove the stopper to avoid loss of the lyophilized pellet and add exactly 5.0 ml distilled or de-ionized water.
5.3.5.4 Leave to stand for 20 minutes. Mix bottle several times by inversion to allow homogeneity
5.3.5.5 Gently invert just prior to use. Avoid foaming.
5.3.5.6 Open the bottle, place a minimum of 1000 ul of each level in separate sample cup, and place on the assigned positions.
5.3.5.7 Cap the bottle tightly and store at 2-8°C immediately after use.
5.3.5.8 Perform QC as indicated in Operator Guide of DimensionEXL200 ,Synchron DXC700 and Atelica CI.

5.3.6 QC Expected Values:
5.3.6.1 Refer to the Bio-Rad Lyphochek assayed chemistry controls value sheet for DimensionEXL200, Synchron DXC700 and Atelica CI.

6. RESPONSIBILITIES:

6.1 Chemistry shift on charge is responsible for, running calibration and control and samples of LA.
6.2 Chemistry staff are responsible for running LA 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, and machine operator.

9. APPROVALS:

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