HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

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

2. DEFINITONS:

2.1 An alkaline phosphatase level test (ALP test) measures the amount of alkaline phosphatase enzyme in bloodstream. Alkaline phosphatase analysis is important for cases with biliary and bone disorders.

3. POLICY:

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

3.2 Alkaline phosphatase includes several iso forms; liver, bone, kidney, intestinal, placental and Regan iso forms. The liver and bone iso forms are particularly important.

3.3 Alkaline Phosphatase raises in obstructive liver diseases, Paget's disease, rickets, osteomalacia, hyperthyroidism and hyperparathyroidism, some drugs (estrogen, erythromycin) and decreases in hypothyroidism, pernicious anemia, hypophosphatemia and malnutrition.

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 of sample required:

4.1.3.1 2.0 to 3.0 ml

4.1.4 Delivery:

4.1.4.1 Sample to be delivered to the lab as soon as possible. If the sample is serum, ensure 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

pH = 10.35
Mg/Zn
ALP
p - NPP + AMP ---------- p -NP + AMP + PO4
p - NPP= p-nitrophenylphosphate
AMP = amino-2-methyl-1-propanol
p – NP = p-nitrophenol

4.2.2 The change in absorbance due to formation of p-NP is directly proportional to the Alkaline Phosphatase concentration in the sample and is measured photo metrically by increase in absorbance at 450 and 480 nm.

4.2.3 Refer to reagent leaflet of kits of DimensionEXL200 ,Synchron DXC700 and Atelica CI machines.

4.3 **Method:**

4.3.1 See policy of loading sample on machine (Ref: Operative Manual of DimensionEXL200 ,Synchron DXC700 and Atelica CI .)

4.4 **Calculation:**

4.4.1 Instrument system automatically calculates the Analytic activity and gives results as print outs

4.5 **Format:**

4.5.1 Numeric

4.6 **Reference:**

4.6.1 Serum/plasma: 46 — 116 U/L

4.7 **Dilution information:**

4.7.1 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:

4.7.1.1 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 dilution factor to automatically correct the concentration by multiplying the result by factor.

4.7.1.3 If the operator does not enter the dilution factor, the result must be multiplied 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 result. Prepare an appropriate dilution/concentration and rerun.

4.8 **Linearity:**

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

4.8.2 ALP is leaner up to 1000 U/L

4.9 **Limit of Detection:**

4.9.1 The Limit of Detection is 10 U/L

5. MATERIALS AND EQUIPMENT:

5.1 **Reagents:**

5.1.1 ALP flex contains 8 wells with the following ingredients:

Reactive Ingredients	Ingredients Concentration
Liquid (1-6 wells) reagent 1	
2-Amino-2-Methyl-I-Propanol (AMP)	3.0 M
Magnesium Acetate	8.0 mmol/L
Zinc Sulfate	4.0 mmol/L
HEDTA	8.0 mmol/L
Liquid (7-8 wells) reagent 2	
p-NPP Buffer	101.6 mmol/L

5.1.2 Reagent Preparation: The mixing and dilutions are automatically performed by the Dimension system

5.1.3 Estimated test per cassette, 90 tests

5.1.4 Analytical Range: 5-1000 ug/dL

5.1.5 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.

5.1.6 Refer to reagent leaflet of kits of DimensionEXL200 ,Synchron DXC700 and Atelica CI .machines.

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 compete 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 2-8° C for 24hr, 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.

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 .machines

5.2.4 Calibration Expected Values: Refer to ALPI CAL for DimensionEXL200 ,Synchron DXC700 and Atelica CI machines.

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, 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 Expected Values:

5.3.3.1 Refer to the Biorad Lyphochek assayed chemistry controls value sheet for DimensionEXL200 ,Synchron DXC700 and Atelica CI .

5.3.4 QC Procedure:

5.3.4.1 Verify that the correct QC values have been entered into the QC file. For details refer to Operator Guide of DimensionEXL200 ,Synchron DXC700 and Atelica CI machines.

5.3.4.2 Allow QC to come to room temperature.

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

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

5.3.4.5 Gently invert just prior to use. Avoid foaming.

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

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

5.3.4.8 Perform QC as indicated in Operator Guide of DimensionEXL200 ,Synchron DXC700 and Atelica CI machines.

6. RESPONSIBILITIES:

6.1 Chemistry shift in charge is responsible for, running calibration, control, and samples of ALP.

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

7. APPENDICES:

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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