HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND
CHILDREN HOSPITAL

Department:	Laboratory and blood bank (Chemistry)		
Document:	Internal Policy and Procedure		
Title:	Analysis of Alanine Aminotransferase Level		
Applies To:	All Laboratory Staff		
Preparation Date:	January 06, 2025	**Index No:**	LB-IPP-151
Approval Date:	January 20, 2025	**Version :**	2
Effective Date:	February 20, 2025	**Replacement No.:**	LB-IPP-151(1)
Review Date:	February 20, 2028	**No. of Pages:**	03

1. PURPOSE:

1.1 The purpose of this policy & procedure is to provide all information related to the analysis of ALT level in blood(serum/plasma) on DimensionEXL200 ,Synchron DXC700 and Atelica CI . machines.

2. DEFINITONS:

2.1 ALT is an enzyme widely reported as present in a variety of tissues.

3. POLICY:

3.1 It is a test used for quantitative determination of the level of the enzyme Alanine Aminotransferase (ALT) in the human serum or plasma on Dimension machines.

3.2 ALT enzyme is present in a variety of tissues. ALT can be elevated in viral or bacterial or toxic hepatitis, cirrhosis, chronic alcohol abuse, obstructive jaundice and slightly elevated in patients who have an uncomplicated myocardial infarction.

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 or 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:**

ALT
L-Alanine + Ketoglutarate ----------> pyruvate + L-glutamate
LDH
Pyruvate + NADH + H+ ----------> L-lactate + NAD+

4.2.1 The rate of the NADH oxidation is directly proportional to the catalytic ALT activity and is measured using a biochromatic (340, 700 nm) rate technique.

4.3 **Calibration:**

4.3.1 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.

4.3.2 Calibration must be done when:

4.3.2.1 A reagent kit with new lot number is used
4.3.2.2 A new assay file that requires a calibration is installed
4.3.2.3 QC fails to meet the established criteria
4.3.2.4 After major maintenance or service
4.3.2.5 When recommended by the manufacturer
4.3.2.6 At least every 6 months

4.3.3 Calibrator retention: 30 days at 2 — 8 °C

4.3.4 Calibration Procedure:

4.3.4.1 Calibration is performed by running Distilled Water and 3 levels of ENZ 11 calibrator Dimension machine. Refer to DimensionEXL200 ,Synchron DXC700 and Atelica CI . calibrator leaflet.

4.4 **Quality control:**

4.4.1 Normal and pathological control. One time in 24 hours (once per day)

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

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

4.4.4 Quality Control retention:

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

4.4.4.2 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. MATERIALS AND EQUIPMENT:

5.1 **Use ALTI flex Cat. No. DF143 contains 8 wells with the following ingredients:**

5.1.1 Dimension (EXL): Use ALTI flex Cat contains 8 wells with the following ingredients:

Reactive Ingredients	Ingredients Concentration
Tablet (1-3 wells)	
LDH	/3000 UL
NADH	0.22 mmol/L
P5P	15 mmol/L
Activators and stabilizers	
Tablet(4-6 wells)	
A-Kg	20 mmol/L
Liquid(7 wells)	
Alanine	260 mmol/L
Liquid(8 wells)	
Tris buffer	100 mmol/l

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 cassette, 60 tests

5.1.2.3 DimensionEXL200 ,Synchron DXC700 and Atelica CI .kit leaflet

5.2 **Analytical Range:**

5.2.1 Serum/Plasma 6-1000 U/L

5.3 **Regents retention:**

5.3.1 Dimension Reagents:

5.3.1.1 The unopened reagents are stable until the expiration date, when stored at 2-8^{0}C.

5.3.1.2 Reagent stability is 30 days if the reagent is unopened and for 3 days if the reagent is opened 1-6 wells and 30 days if opened 7-8 wells.

5.3.2 DimensionEXL200 ,Synchron DXC700 and Atelica CI .reagents

6. RESPONSIBILITIES:

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

6.2 Chemistry staff are responsible for running ALT 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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