HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Chemistry)		
Document:	Internal Policy and Procedure		
Title:	Analysis of Ammonia Level		
Applies To:	All Laboratory Staff		
Preparation Date:	January 06, 2025	**Index No:**	LB-IPP-152
Approval Date:	January 20, 2025	**Version :**	2
Effective Date:	February 20, 2025	**Replacement No.:**	LB-IPP-152(1)
Review Date:	February 20, 2028	**No. of Pages:**	04

1. PURPOSE:

1.1 The purpose of this policy and procedure is to provide all information related to the analysis of ammonia level in blood (serum/plasma) on DimensionEXL200.

2. DEFINITONS:

2.1 N/A

3. POLICY:

3.1 This policy provides instructions for performing the quantitative determination of ammonia in human plasma onDimensionEXL200.
3.2 It is a diagnostic test as an in vitro diagnostic test for quantitative determination of the level of ammonia inhuman plasma.
3.3 Plasma NH3 level is increased in: inherited metabolic defects, Hepatic encephalopathy, drugs e.g. (Diuretics, Methicillin), Acute hepatic necrosis, terminal portal cirrhosis, Reyes Syndrome.
3.4 Plasma NH3 level is decreased in: renal failure, drugs e.g. (neomycin, lactulose, tetracycline).

4. PROCEDURE:

4.1 **Specimen Type:**
4.1.1 Plasma
4.2 **Tube Type:**
4.2.1 Lithium heparin EDTA tube with ice
4.3 **Amount Required:**
4.3.1 2.0 to 3.0 ml.
4.4 Call the lab before sampling
4.5 **Delivery Arrangements:**
4.5.1 Sample to be delivered to the lab as soon as possible.
4.6 **Unacceptable Specimen:**
4.6.1 See sample rejection criteria policy.
4.7 **Safety Precaution:**
4.7.1 Treat all samples material as infectious and handled in accordance with the OHSA standard on blood borne pathogens.
4.8 **Principle:**
4.8.1 Refer to kit leaflet of DimensionEXL200.
4.9 **Method:**
4.9.1 See policy of loading sample on machine (Ref: Operative Manuals' of Dimenstion EXL200).
4.10 **Calculation:**
4.10.1 Instrument system automatically calculates the Analytic activity and gives results in the form of print outs.

4.11 **Reference ranges:**

4.11.1 Dimension ExL200: Plasma 11 — 32 Umol/L

4.12 **Test Limitation:**

4.12.1 Refer to kit leaflet

4.13 **Linearity:**

4.13.1 Refer to kit leaflet

5. MATERIALS AND EQUIPMENT:

5.1 **Reagents:**

5.1.1 Ammonia flex contains 6 wells with the following ingredients:

Reactive Ingredients	Ingredients Concentration
Liquid (1-6 wells)	
a-ketoglutarate	10 mmol/L
GLDH	>24 KU/L
NADPH	0.2 mmol/L

5.1.2 Reagent Preparation:

5.1.2.1 Mixing and diluting are automatically performed by the Dimension system

5.1.3 Estimated test per cassette, 120 tests

Analytical Range: Plasma (0 — 1000 umoUL)

5.1.4 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 3 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 compete change of reagents that affects the range used to report patient results or QC values

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 For 24 hours at 2 — 8 °C, 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.

5.2.4 Calibration Expected Values: Refer to CHEM III calibrator for Dimension.

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 Expected Values: Refer to the Biorad Lyphochek assayed chemistry controls value sheet for DimensionEXL200.

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 and SynchronDXC600 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

5.3.4.5 Mix bottle several times by inversion to allow homogeneity

5.3.4.6 Gently invert just prior to use. Avoid foaming

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

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

5.3.4.9 Perform QC as indicated in Operator Guide of DimensionEXL200 and SynchronDXC600 machines

6. RESPONSIBILITIES:

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

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

7. APPENDICES:

7.1 N/A

8. REFERENCES:

8.1 Tietze Text Book of clinical chemistry and molecular diagnostics 4th Edition, 2006.

8.2 Company Leaflets of reagents.

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Dr. Talal Abdelgawad	Clinical Pathologist		January 06, 2025
Reviewed by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		January 13, 2025
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		January 13, 2025
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 13, 2025
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		January 13, 2025
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 20, 2025