HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND
CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Chemistry)		
Document:	Internal Policy and Procedure		
Title:	Analysis of Uric Acid Level		
Applies To:	All Laboratory Staff		
Preparation Date:	January 02, 2025	**Index No:**	LB-IPP-034
Approval Date:	January 16, 2025	**Version:**	2
Effective Date:	February 16, 2025	**Replacement No.:**	LB-IPP-034(1)
Review Date:	February 16, 2028	**No. of Pages:**	04

1. PURPOSE:

1.1 The purpose of this policy & procedure is to provide all information related to the analysis of uric acid level in blood (serum/plasma) and urine on Dimension EXL200 ,Synchron DXC700 and Atelica CI .machines.

2. DEFINITONS:

N/A

3. POLICY:

3.1 This policy provides instructions for performing the quantitative determination of uric acid in human serum, plasma or urine on Dimension EXL200 ,Synchron DXC700 and Atelica CI .machines.

3.2 It is a test used to assess the level of uric acid in blood or urine of patient to know wither the patient is normouricemic, hypouricemic or hyperuricemic with its consequences.

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 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:**

Uric acid + 2 H2O + 02 -------uricase------→ allantoin + CO2 + H202
H202 +(H+)+ TOOSa +4-aminophenazone------- Peroxidase-----→ quinone-diimine dye + 4 H2O

4.2.1 The colour intensity of the quinone-diimine formed is directly proportional to the uric acid concentration and is determined by measuring the increase in absorbance at 546 and 700 nm.

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 printout.

4.5 **Format:**

4.5.1 Numeric

4.6 **Status:**

4.6.1 Stat and Routine

4.7 **Reference ranges:**

4.7.1 Serum/plasma 0.1547- 0.4283 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 Uric Acid is leaner up 1.189mmol/L

4.10 **Limit of Detection:**

4.10.1 The Limit of Detection is 0

5. MATERIALS AND EQUIPMENT:

5.1 **Reagent:**

5.1.1 Refer to uric acid leaflet of DimensionEXL200 ,Synchron DXC700 and Atelica CI .

5.1.1.1 Analytical Range: Serum/plasma 0 - 20.0 mg/dL (0 -1190 limol/L)

5.1.1.2 Estimated test per flex, 60 tests

5.1.2 Regents retention:

5.1.2.1 The unopened reagents are stable until the expiration date when stored at 2-8U. Reagent stability is 30 days if the reagent is unopened and for 5 days if the reagent is opened 1-6 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.
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 .

5.2.4 Calibration Expected Values:
5.2.4.1 Refer to CHEM I calibrator for DimensionEXL200 ,Synchron DXC700 and Atelica CI operator manual.

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 analytics will be stable for 7 days except Bilirubin (Direct) for 4 days at 2 — 8 °C, All analytics 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 ,Synchron DXC700 and Atelica CI .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 ,Synchron DXC700 and Atelica CI .machines.

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

6. RESPONSIBILITIES:

6.1 Chemistry shift in charge is responsible for, running calibration and control and samples
6.2 Chemistry staff are responsible for running glucose 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:

	Name	Title	Signature	Date
Prepared by:	Dr. Talal Abdelgawad	Clinical Pathologist		January 02, 2025
Reviewed by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		January 08, 2025
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		January 09, 2025
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 12, 2025
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		January 12, 2025
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 16, 2025