HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Chemistry)		
Document:	Internal Policy and Procedure		
Title:	Analysis of Micro-Albumin 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 very small quantity of albumin level in patient urine on DimensionEXL200 machines.

2. DEFINITONS:

2.1 A micro albumin test is used to detect early signs of kidney damage in people who are at risk of developing kidney disease.

3. POLICY:

3.1 This policy provides instructions for performing the quantitative determination of the very small quantity of albumin in patient urine on DimensionEXL200 machine.

3.2 A micro albumin test is used to detect early signs of kidney damage in people who are at risk of developing kidney disease.

4. PROCEDURE:

4.1 **Specimen:**

- 4.1.1 Type: Urine
- 4.1.2 Tube Type: Sterile container for urine
- 4.1.3 Amount Required: 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.
- 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:**

PR + Ab + ALB (sample) ----------> PR + Ab + ALB (sample)
PR = Particle reagent consisting of synthetic particles with human albumin bound to the surface
Ab= Antibody to human albumin
ALB= Albumin

4.2.1 The rate of aggregation is inversely proportional to the concentration of albumin in sample. The rate of aggregation is measured using biochromatic turbidimetric reading at 340 and 700 nm.

4.3 **Method:**

4.3.1 See policy of loading sample on machine (Ref: Operative Manuals' of Dimension ExL200

4.4 **Calculation:**

4.4.1 Instrument system automatically calculates the Analytic activity and gives results in the form of printout.

4.5 **Format:** Numeric

4.6 **Status:** Stat and Routine

4.7 **Reference ranges:**

4.7.1 Urine 1.3 - 20 mg/L

4.8 **Linearity:**

4.8.1 MALB is leaner up to 100 mg/L

4.9 **Limit of Detection:**

4.9.1 The Limit of Detection is 1.3 mg/L

5. MATERIALS AND EQUIPMENT:

5.1 **Reagent:**

5.1.1 MALB flex Cat. No. DF114 contains 8 wells with the following ingredients:

Reactive Ingredients	Ingredient Concentration
Liquid 1-2 wells)	
Particle Reagent	Mg/mi
Microbial inhibitors	
Liquid 3-6wells)	
NaOH+	0.5 N
Liquid 4-5 wells)	
Antibody to human albumin	140 ug/dL
Microbial inhibitors	
Liquid 7-8 wells)	
Buffer	
Microbial inhibitors	

5.1.1.1 Reagent Preparation:

5.1.1.1.1 Mixing and diluting are automatically performed by the Dimension system

5.1.1.1.2 Estimated test per cassette, 20 tests

5.1.1.1.3 Analytical Range: Urine (1.3 - 100 mg/dL)

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 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 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 and SynchronDXC600 .

5.2.4 Calibration Expected Values:

5.2.4.1 Refer to micro albumen 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 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 and SynchronDXC600 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 and SynchronDXC600 machines.

5.3.4 QC Expected Values:

5.3.4.1 Refer to the Bio-Rad Lyphochek assayed chemistry controls value sheet for Dimension.

6. RESPONSIBILITIES:

6.1 Chemistry shift on charge is responsible for, running calibration and control and samples of microalbumin.

6.2 Chemistry staff are responsible for running microalbumin 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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