Brown Clinic Northridge
511 14th Ave. NE
Watertown, SD

Brown Clinic
506 First Ave. SE
Watertown, SD

BROWN CLINIC
LABORATORY PROCEDURE MANUAL

PROCEDURE: Microalbumin

PURPOSE:
The MALB Flex® reagent cartridge used on the Dimension EXL200 Integrated chemistry system is an *in vitro* diagnostic test intended to quantitatively measure albumin in **human urine**.

PRINCIPLE:
Diabetic nephropathy occurs in 20 – 40% of patients with diabetes and is the single leading cause of end-stage renal disease. Measurements of albumin in urine are used as an aid in monitoring the development of incipient diabetic nephropathy and for the diagnosis and treatment of a variety of diseases characterized by albuminuria.[1]

The Microalbumin (MALB) method is based on a particle-enhanced turbidimetric inhibition immunoassay (PETINIA) adapted to the Dimension® clinical chemistry system which allows direct quantitation of albumin in urine samples. The MALB Flex® reagent cartridge contains a particle reagent (PR) consisting of synthetic particles with human albumin bound to the surface. Aggregates of these particles are formed when a monoclonal antibody (Ab) to human albumin is introduced. Albumin (ALB) present in the sample competes with the particles for the antibody, thereby decreasing the rate of aggregation. Hence, the rate of aggregation is inversely proportional to the concentration of albumin in the sample. The rate of aggregation is measured using bichromatic turbidimetric reading at 340 and 700 nm. The concentration is determined by means of a mathematical function.

PR + Ab + ALB (sample) ———> PR-Ab complex + Ab - ALB
(scatters light at 340 nm)

INSTRUMENT, REAGENTS & SUPPLIES:

Wells [a]		Form	Ingredient	Concentration [b]	Source
1,2	Liquid	Particle Reagent Microbial inhibitors	2 mg/mL[c]		
3,6	Liquid	NaOH[d]	0.5 N		
4,5	Liquid	Antibody to human albumin Microbial inhibitors	140 µg/mL[c]	Mouse, monoclonal	
7,8	Liquid	Buffer			

a. Wells are numbered consecutively from the wide end of the cartridge.
b. Nominal value per well in a cartridge.
c. The particle reagent and antibody are a matched pair and may vary from lot to lot.
d. Sodium hydroxide is used as a probe cleaning solution and is not used in the reaction.

Risk and Safety:
H290, H314, H317
P280, P304 + P340 + P310, P301 + P310 + P331, P303 + P361 + P353 + P310, P305 + P310, P501
Danger!
May be corrosive to metals. Causes severe skin burns and eye damage. May cause an allergic skin reaction.
Wear protective gloves/protective clothing/eye protection/face protection. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/physician. IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Do NOT induce vomiting. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician. IF IN EYES: Immediately call a POISON CENTER or doctor/physician. Dispose of contents and container in accordance with all local, regional, and national regulations.
Contains: Sodium hydroxide; 5-chloro-2-methyl-3(2h)-isothiazolone mixture with 2-methyl-3(2h)-isothiazolone.

Precautions:

Used cuvettes contain human body fluids. Handle with appropriate care to avoid skin contact and ingestion.

For *in vitro* diagnostic use.

Safety Data Sheets (SDS/MSDS) can be found at www.siemens.com/healthcare

REAGENT STORAGE & STABILITY:
Store at 2 - 8 °C.

Reagent Stability: Refer to carton for expiration date of individual unopened reagent cartridges. Sealed cartridge wells on the instrument are stable for 30 days. Once wells 1 through 8 have been entered by the instrument the stability is 3 days.

SPECIMEN REQUIREMENTS:
Normal procedures for collecting urine may be used for samples to be analyzed by this method. The following samples are acceptable:

1. 24-hour collection
2. Overnight (8-12-hour) collection
3. 1-to 2-hour collection
4. First-morning sample for simultaneous albumin and creatinine measurement.

Samples should not be collected after exertion, in the presence of urinary tract infection, during acute illness, immediately after surgery, or after an acute fluid load. Specimens should be

collected without preservatives. Specimens visibly contaminated with blood are not suitable for analysis of albumin concentration.

Specimen:

- patient preparation: see notes above
- specimen type: see notes above
- stability: Room temperature: 2 days
  Refrigerated at 2-8°C: 14 days
  Frozen at -20°C: not recommended

CONTROLS:

At least once daily run solutions at two levels of a quality control material with known concentrations.

For further details, refer to your Dimension® system manual. The result obtained should fall within limits defined by the day-to-day variability of the system as measured in the user's laboratory. If the results fall outside the laboratory's acceptable limits, follow the procedure in the quality control policy.

PROCEDURE:

Materials Provided

The MALB Flex® reagent cartridge, Cat No. DF114

Materials Required but not Provided

Dimension® Microalbumin Calibrator, Cat No. DC114
Quality Control materials

Test Steps

Sampling, reagent delivery, mixing, processing, and printing of results are automatically performed by the Dimension® system. For details of this processing, refer to your Dimension® system manual.

The sample container must contain sufficient quantity to accommodate the sample volume plus dead volume. Precise container filling is not required.

Test Conditions

Sample Size	17 µL
Particle Reagent Volume	76 µL
Antibody Reagent Volume	76 µL
Assay Buffer Volume	288 µL
Test Temperature	37 °C
Wavelengths	340 and 700 nm
Type of Measurement	turbidimetric rate

Calibration

The general calibration procedure is described in your Dimension® system manual. The following information should be considered when calibrating the MALB method:

Assay Range:	1.3 – 100 mg/L
Reference Material:	Microalbumin Calibrator, REF DC114

Suggested Calibration Levels:	0, 12.5, 25.0, 50.0, 110.0 mg/L
Calibration Scheme:	Five levels in duplicate
Calibration Frequency:	Every new reagent cartridge lot
	Every 30 days for any one lot
	For each new lot of Flex reagent cartridges
	After major maintenance or service, if indicated by quality control results
	As indicated in laboratory quality control procedures
	When required by government regulations

Assigned Coefficients: C_0: 590, C_1: -605, C_2: -1.6, C_3: 37.4, C_4: 0.5

Backup Process:
Refer to Brown Clinic Back-up Policy

INTERPRETATION:
The instrument automatically calculates and prints the concentration of microalbumin in mg/L using the calculation scheme illustrated in your Dimension® system manual.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

EXPECTED VALUES:

Less than 20 µg/min [g]
Less than 30 mg/24 hour
Excretion rate: less than 30 mg albumin/g creatinine [h]

g. MALB (mg/L) x [Urine Volume (mL) / Time (minutes)] = µg MALB/min
h. [MALB (mg/L) / Urine creatinine (mg/dL)] x 100 = mg MALB/g creatinine

To minimize intra-individual variation, analysis of three random urine samples collected over the course of a week has also been recommended.[1] Each laboratory should establish its own reference interval for microalbumin as performed on the Dimension®system.

REPORTING:
Report format: ug/min

LIMITATIONS:

Results:	> 100 mg/L should be diluted.
Manual dilution:	Make appropriate dilution with reagent grade water or Microalbumin Calibrator (REF DC114), Level 1, to obtain results within the assay range. Enter dilution factor. Reassay. Resulting readout is corrected for dilution.
Autodilution:	Refer to your Dimension® system manual. The recommended autodilute volume is 2 µL
Results:	< 1.3 mg/L report as "less than 1.3 mg/L" instead of the numerical value.

The instrument reporting system contains error messages to warn the user of specific malfunctions. MALB results followed by such error messages should be held for follow-up. Refer to your Dimension® system manual.

Analytical Specificity

For Known Interfering Substances section refer to package insert.

For Known Non-Interfering Substance refer to package insert.

For Additional Technical Information refer to package insert.

Reference: MALB Flex® reagent cartridge insert sheet PN 717114.001 Issue Date 2015-03-09

Origination Date: 9-10-07
Date of Implementation: 11-10-10
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Written By: ____Lori Murray MT(ASCP)_____ Date: _8-8-12

Approved By: _____Aaron Shives, MD_____ Date: __10/21/2017____
Laboratory Director

REVIEW - REVISION SUMMARY DOCUMENTATION

Date	By	Revision Summary
07/10	Lori Murray	New format
8-8-12	Lori Murray	Changed instrumentation to EXL200
6/3/15	Heather Hall	Updated to information from package insert dated 3/4/2008
8-27-15	Sam Legg	Added Risk and Safety per package insert dated 3-9-15
10/18/17	Heather Hall	Modified Backup method