

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

K033525

B. Analyte:

Urinary albumin (microalbumin)

C. Type of Test:

Quantitative particle-enhanced turbidimetric inhibition immunoassay (PETINIA)

D. Applicant:

Dade Behring, Inc.

E. Proprietary and Established Names:

Dimension[®] Microalbumin (MALB) Flex[®] reagent cartridge

Dimension[®] Microalbumin calibrator

F. Regulatory Information:

1. Regulation section:
21 CFR § 866.5040 (reagent)
21 CFR § 862.1150 (calibrator)
2. Classification:
Class II
3. Product Code:
DCF (reagent)
JIT (calibrator)
4. Panel:
Immunology

G. Intended Use:

1. Indication(s) for use:

The Dade Behring Dimension[®] Microalbumin (MALB) Flex[®] reagent cartridge method is an *in vitro* diagnostic test intended to quantitatively measure albumin in human urine. Measurement of albumin aids in the diagnosis of kidney and intestinal diseases. Measurement also aids in the diagnosis and treatment of heart diseases or thyroid disorders which are characterized by proteinuria or albuminuria.

The Dade Behring Dimension[®] Microalbumin Calibrator is an *in vitro* diagnostic device intended for use on Dade Behring Dimension[®] clinical chemistry systems for medical purposes to establish points of reference that are used in the determination of albumin in urine.

2. Special condition for use statement(s):
Prescription use only
3. Special instrument Requirements:
Dimension® clinical chemistry system only

H. Device Description:

The MALB reagent consists of particle reagent (2 mg/mL), mouse monoclonal antibodies to human albumin (140 µg/mL), microbial inhibitors, and buffer.

The MALB Calibrator is a buffered aqueous product containing weighed-in quantities of human albumin. The calibrator is packaged as a 5-level kit at nominal albumin concentrations of 0, 12.5, 25, 50, and 110 mg/L. Quality control material is not included with the reagent and calibrator.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Dade Behring nephelometric (BN II) N Antiserum to Human Albumin assay;
Dade Behring Urinary Albumin Calibrator
2. Predicate K number(s):
K972929; K936201
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Matrix	Urine	Urine, Serum, CSF
Analyzer	Same	Dade Automated Analyzer
Methodology	Same	Light-scattering
Calibrator	Human based, 5 levels	Human based, 3 levels
Differences		
Item	Device	Predicate
Reportable Range	1.3 – 100 mg/L	2.2 – 340 mg/L
Sample Size	17 µL	80 µL

J. Standard/Guidance Document Referenced (if applicable):

None referenced

K. Test Principle:

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 latex 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 readings at 340 and 700 nm. The concentration is determined by means of a mathematical function.

PR + Ab + ALB (sample)