

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

A. 510(k) Number:

k050576

B. Purpose for Submission:

Notification of intent to manufacture and market the device: Microalbumin TIA reagent, calibrator set and controls

C. Measurand:

Microalbumin

D. Type of Test:

Quantitative, turbidometric immunoassay

E. Applicant:

Good Biotech Corporation

F. Proprietary and Established Names:

Proprietary Names

Microalbumin TIA Reagent
mAlb Calibrator Set 200
mAlb Control-L, Control-H

Established Names

Urinary albumin immunological test system
Urinary albumin calibrator
Urinary albumin controls

G. Regulatory Information:

1. Regulation section:

Microalbumin TIA Reagent - 21 CFR 866.5040
mAlb Calibrator Set 200 - 21 CFR 862.1150

mAlb Control-L, Control-H - 21 CFR 862.1660

2. Classification:

Microalbumin TIA Reagent – Class II (Special Controls) This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 866.9 subpart (c) (5).

mAlb Calibrator Set 200 – Class II

mAlb Control-L, Control-H – Class I

3. Product code:

Microalbumin TIA Reagent - DDZ

mAlb Calibrator Set 200 - JIT

mAlb Control-L, Control-H - JJX

4. Panel:

Microalbumin TIA Reagent 81 Immunology

mAlb Calibrator Set 200 75 Chemistry

mAlb Control-L, Control-H 75 Chemistry

H. Intended Use:

1. Intended use(s):

Please see indications for use below

2. Indication(s) for use:

Good Biotech Corp. (GBC) Microalbumin test system is intended to be used for the quantitative determination of low level albumin in human urine by turbidometric immunoassay (TIA). Measurement of albumin aids in the diagnosis of kidney disease.

GBC mAlb Calibrator Set 200 is intended to be used with GBC Microalbumin TIA for the quantitative determination of microalbumin in urine samples.

GBC Microalbumin Controls are to be used as the assayed quality control material for the urinary albumin analysis.

For In Vitro Diagnostic Use

3. Special conditions for use statement(s):

For professional use only

4. Special instrument requirements:

Microalbumin TIA is a “ready to use” reagent kit for clinical chemistry auto-analyzers. Microalbumin TIA has been tested on the Hitachi 911 Clinical Chemistry analyzer.

I. Device Description:

Microalbumin TIA consists of a “ready to use” reagent kit - Reagent 1 (reactive buffer solution) and Reagent 2 (antibody solution) in a one kit set. The antibody consists of a duck anti-albumin from purified duck yolk. The host ducks are domestic stock and are inoculated to prevent avian associated diseases.

The calibrators consist of 5 levels of albumin in 2 mL bottles. They are provided in liquid form. The calibrators are prepared from human sera which were found to be negative for HbsAg, anti-HIV1 and 2 antibodies and anti-HCV antibody.

The controls consist of 2 levels of albumin in 1.5 mL bottles. They are provided in liquid form. The controls are prepared from human sera which were found to be negative for HbsAg, anti-HIV1 and 2 antibodies and anti-HCV antibody by FDA licensed methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Randox Microalbumin Test kit, Wako Micro-Albumin B/Wako Micro Albumin Calibrator

2. Predicate 510(k) number(s):

k002674, k944664

3. Comparison with predicate:

Item	Device	Predicate	
Name	Microalbumin TIA mAlb Calibrator Set 200 mAlb Control-L, Control-H	Randox Microalbumin Test kit	Wako Micro-Albumin B/ Wako Micro Albumin Calibrator
Reagent			
Intended Use	Same	For the quantitative in vitro determination of Microalbumin in urine	Same
Methodology	Same	Turbidimetric ImmunoAssay	Same
Composition	Reactive Buffer Solution (R1): Tris buffer Antibody Solution (R2): Duck anti-human albumin antibody	Assay Buffer: PEG, Tris/HCl buffer, NaCl Antibody Reagent: Anti-human albumin, Tris/HCl buffer, NaCl	Buffer: Good's buffer, NaN ₃ Antibody B: Rabbit anti-human albumin antibody, mouse anti-human albumin antibody, NaN ₃
Sample Volume	Same	20 µl/test	Same
Reagent Volume	R1: 250 µl/test R2: 30 µl/test	Assay Buffer: 250 µl/test Antibody Reagent: 25 µl/test	Buffer: 300 µl/test Antibody B: 100 µl/test
Wavelength	Main/sub:340 nm/ 700 nm	Main/sub:340 nm/ -	Main/sub:340 nm/ 700 nm
Interference	No interference to: ascorbic acid (250 mg/dL), glucose (10000 mg/dL), urea (4000 mg/dL), uric acid (100 mg/dL), creatine (50 mg/dL), creatinine (2000 mg/dL), urobilinogen (20 mg/dL), bilirubin (30 mg/dL), hemoglobin (300 mg/dL), IgG (50 mg/dL), calcium (75 mg/dL), magnesium (75 mg/dL), inorganic phosphorus (50 mg/dL), potassium chloride (2000 mg/dL), sodium chloride (2000 mg/dL), chloroform (1000 µg/dL), toluene (1000 µg/dL), xylene (1000 µg/dL), thymol (50000 µg/dL) and formalin (750 µg/dL)	No interference to: ascorbic acid (4 g/l), bilirubin (250 mg/l), creatinine (4 g/l), gentamicin (10 g/l), glucose (40 g/l), paracetamol (5 g/l), potassium chloride (10 g/l), sodium chloride (20 g/l), urea (40 g/l)	No interference to: ascorbic acid (400 mg/dL), glucose (4000 mg/dL), uric acid (100 mg/dL), urea (400 mg/dL), creatinine (400 mg/dL), sodium chloride (2000 mg/dL), potassium chloride (1000 mg/dL), calcium (100 mg/dL), inorganic phosphorus (400 mg/dL), hippuric acid (400 mg/dL), hemoglobin (500 mg/dL), bilirubin (25 mg/dL), urobilinogen (20 mg/dL), 6N hydrochloric acid (4 mL/dL), toluene (1000 µg/dL), xylene (1000 µg/dL), chloroform (1000µg/dL), formalin (1000 µg/dL), acetic acid (1000 µg/dL)
Calibrator/ Control			
Target Analyte	Same	Human serum albumin	Same
Preservative	Same	Sodium Azide	Same
Preparation	Calibrator: liquid (ready-to- use) Control: liquid (ready-to-use)	Calibrator: liquid (ready-to- use) Control: powder (reconstitution by redistilled water)	Calibrator: liquid (ready-to- use)

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

Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro
Diagnostic Calibrators; Final FOD 1247

Guidance for Industry and FDA Staff; Replacement Reagent and Instrument

Family Policy FOD 950

Shelf Life of Medical Devices FOD 415

CLSI document EP14-A Evaluation of Matrix Effects; Approved Guidelines.

L. Test Principle:

Immunoturbidometric

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

With-in run precision was established by assaying 2 samples for 20 times. The results are as follows:

Within-run precision

Sample #	Replicates	Mean (mg/L)	S.D.	CV(%)
I	20	18.77	0.385	2.049
II	20	57.28	1.029	1.797

Total precision was established by assaying 2 samples in duplicate twice a day for 20 days. The results are as follows:

Total Precision

Number of Assay Days	Mean (mg/L)	S.D.	CV(%)	S _{wr}	S _T
20	20.56	1.431	6.96	0.598	1.804
20	45.28	2.132	4.71	0.699	2.872

b. *Linearity/assay reportable range:*

Linearity was established using a range of dilutions from a 200 mg/L albumin urine sample. The R² value obtained from the linear regression was 0.9966. Linearity was established from 0 to 200 mg/L.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The assigned albumin values of the GBC mAlb calibrator set 200 and

GBC Microalbumin Controls are determined by the turbidometric immunoassay and are traceable to the IFCC/BCR/CAP reference material CRM 470.

The accelerated stability studies were performed to predict the shelf life of mAlb set 200 and Microalbumin controls under recommended storage conditions. The studies were conducted according to FDA-documented *Shelf Life of Medical Devices*, FOD 415.

Stability was determined to be 28 days after opening if stored at 2°C to 10°C. Stability unopened was determined to be 9 months when stored at recommended conditions.

Reagent R1 and R2 are stable up to the expiration date if stored at 2°C to 10°C. R1 and R2 are stable opened and refrigerated at 2°C to 10°C for 30 days.

d. Detection limit:

The detection limit 0.3 mg/L was calculated as 2SD above the mean response of the zero calibrator when assayed 20 times.

e. Analytical specificity:

Interference was defined as above 10% difference with original assay values. Interferents with the following concentrations did not interfere with Microalbumin TIA.

Formalin	750 µg/dL	Uric Acid	100 mg/dL
Thymol	50000 µg/dL	Creatine	200 mg/dL
Chloroform	1000 µg/dL	Creatinine	2000 mg/dL
Toluene	1000 µg/dL	Calcium	75 mg/dL
Xylene	1000 µg/dL	Inorganic Phosphorous	75 mg/dL
Potassium Chloride	2000 mg/dL	IgG	50 mg/dL
Sodium Chloride	2000 mg/dL	Magnesium	75 mg/dL
Ascorbic Acid	250 mg/dL	Urobilinogen	20 mg/dL
Glucose	10000 mg/dL	Hemoglobin	300 mg/dL
Urea	4000 mg/dL	Bilirubin	30 mg/dL

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

50 leftover urine samples were collected. Since extensive patient data was not required in the study, no name or linked identification number linked with the leftover samples was provided. Microalbumin measurements were performed on each sample in duplicate. Each sample was also tested using the predicate devices according to the manufacturer's instructions. Testing was performed on the Roche Diagnostics Hitachi 911 analyzer. The results of regression are shown on the table below:

Test Method	Slope	Y intercept	R ² value	N	Predicate Method
Microalbumin TIA	1.20	-0.56 mg/L	0.997	50	Randox Microalbumin
Microalbumin TIA	1.02	-2.17 mg/L	0.998	50	Wako Micro-Albumin B

b. *Matrix comparison:*

Not Applicable

3. Clinical studies:

a. *Clinical Sensitivity:*

Not Applicable

b. *Clinical specificity:*

Not Applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not Applicable

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

Reference Intervals 24 – h collection: less than 30 mg/24 hour

Timed collection: less than 20 µg/min

Spot collection: less than 30mg/g creatinine

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.