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

A. 510(k) Number:
  k072078
B. Purpose for Submission:
  Addition of the urine matrix to the assay procedure
C. Measurand:
  Beta-2-microglobulin
D. Type of Test:
  Latex particle enhanced immunoturbidimetric assay
E. Applicant:
  Biokit S.A.
F. Proprietary and Established Names:
  Quantia Beta-2 Microglobulin
G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
System, Test, Beta-2-Microglobulin Immunological (JZG)	Class II	21 CFR 866.5630, Beta-2-microglobulin immunological test system.	82 IMMUNOLOGY (IM)

H. Intended Use:
  1. Intended use(s):
     The Quantia Beta-2 Microglobulin is intended as a latex particle enhanced immunoturbidimetric assay for the *in vitro* quantitative determination of beta-2-microglobulin concentration in human serum, plasma (EDTA) or urine on the AEROSET ® Instrument as an aid in the diagnosis of active rheumatoid arthritis and kidney disease.

     The Quantia Beta-2 Microglobulin is intended to be used with the already cleared Quantia PROTEINS Control (k050596) and the Beta-2 Microglobulin Standard (k050613).
  2. Indication(s) for use:
     Same as Intended Use
  3. Special conditions for use statement(s):
     For prescription use only
  4. Special instrument requirements:
     The reagents are for use on the Abbott AEROSET® instrument

I. Device Description:
  The Quantia Beta-2 Microglobulin kit contains 4 bottles of Reagent 1 (R1) (6 mL each) and 4 bottles of Reagent 2 (R2) (3 mL each). R1 buffer is sodium dihydrogen

phosphate dihydrate with polyethylene glycol and preservative (sodium azide). R2 is a suspension of polystyrene latex particles of uniform size coated with the IgG fraction of rabbit anti-human Beta-2-microglobulin specific serum with preservative (sodium azide).

J. Substantial Equivalence Information:

Predicate: IL Test Beta-2-Microglobulin	K943686

Similarities:
The Quantia Beta-2 Microglobulin and the IL Test Beta-2-Microglobulin are both manufactured by Biokit and are both intended for the quantitative *in vitro* diagnostic determination of beta-2-microglubulin. They also use the same methodology: Particle Enhanced Immunoturbidimetry. The Quantia Beta-2 Microglobulin and the IL Test Beta-2- Microglobulin, have the same composition: Latex Reagent Suspension of polystyrene latex particles coated with rabbit IgG anti-human Beta-2 Microglobulin in a buffer containing bovine serum albumin and < 0.1 % w/w sodium azide; and Reaction Buffer Phosphate buffer 40mM containing bovine serum albumin and sodium azide < 0.1 % w/w.

Differences:
Specimen type: both assays can use serum and urine as samples. They differ in the plasma types. The device can use EDTA and the predicate can use EDTA and sodium heparin.

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

STANDARDS
Title and Reference Number
CLSI Interference Testing in Clinical Chemistry; Approved Guideline (EP 7-A)
CLSI Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (EP09-A2)
CLSI Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline (EP5-A)

L. Test Principle:

When a sample containing Beta-2 Microglobulin is mixed with the reagent, a clear agglutination occurs which can be measured by turbidimetry. Results are expressed in mg/L of Beta-2-microglobulin based on the 1st WHO International Standard (B2M) established in 1985.

M. Performance Characteristics (if/when applicable):
1. Analytical performance:
   a. *Precision/Reproducibility:*
      CLSI EP5-A was followed.

Samples/Runs	Mean (mg/L)	CV (%) Within Run	CV (%) Total
2/40	0.066	4.2	5.4
2/40	0.094	1.7	3.1
2/40	0.204	1.5	2.6
2/40	0.302	1.6	2.3

b. *Linearity/assay reportable range:*
Linearity was assessed according to CLSI EP6-A. The overall reportable range for serum, plasma and urine is 0.025 to 96 mg/L. The assay was linear from 0.025 to 1.6 mg/L (the reportable range for urine samples) with the automatic rerun capability (Dilution Protocol 2); from 0.25 to 16 mg/L without the automatic rerun capability; and from16 to 96 mg/L with the automatic rerun capability (Dilution Protocol 1).

Prozone
The manufacturer was asked to run a sample higher than 114 mg/L to demonstrate the instrument give a result of >16 mg/L. They tested samples from 80.4 to 200.9 mg/L. In all cases the instrument gave a result of > 96 (serum linearity upper limit) and triggered the Dilution Protocol 1. The assay did not demonstrate prozone effect with specimens up to 200 mg/L.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The assay calibrators are standardized against WHO reference material B2M. Stability of the reagents was established at 19 months by testing 4 different lots. Reagents should be stored at 2-8°C.

d. *Detection limit*:
The limit of quantitation (LOQ) was defined as the minimum quantity of analyte that can be measured with a within-run CV below 20% and an error below 20%. The LOQ for the assay was determined to be 0.25 mg/L without the automatic rerun capability and 0.025 mg/L with the automatic rerun capability for serum, plasma and urine. This was established by running serial dilutions of the 4 mg/L calibrator. Through 0.025 mg/L the %CV ranged from 1.0 to 5.5% and error ranged from 3.8 to 9.3%.

The limit of detection (LOD) was defined as the mean reported value + 2SD for a sample free of analyte. The LOD was determined to be 0.046 mg/L without the rerun capability and 0.025 mg/L (LOQ) with the automatic rerun capability.

e. *Analytical specificity:*
CLSI guideline EP7-A was followed.

Substance tested	Concentration (mg/dL)	Outcome
Conjugated bilirubin	20.9	No interference
Ascorbic acid	20	Interference below 10%
Hemoglobin	23.6	Interference below 10%
Protein (IgG)	100	No interference

Urine pH showed no significant positive or negative influence on the result.

f. *Assay cut-off:*
   See Expected values/Reference range
2. Comparison studies:
   a. *Method comparison with predicate device:*
      The comparison studies were performed using 110 urine samples with values ranging from 0.01 to 18.85 mg/L. The required specifications were: Slope 1.0 ± 0.20; and correlation coefficient r ≥ 0.950. The following results were obtained:

   AEROSET versus ILab 900

Parameter	Outcome
Slope	1.088 (95% CI: 1.061 to 1.127)
Intercept	-0.001 (95% CI: -0.003 to 0.002)
Range (mg/L)	0.01- 18.85
Mean x (mg/L)	2.47
Mean y (mg/L)	2.467
R	0.9894

   b. *Matrix comparison:*
      Urine was the only matrix compared.

3. Clinical studies:
   a. *Clinical Sensitivity:*
      Not determined
   b. *Clinical specificity:*
      Not determined
   c. Other clinical supportive data (when a. and b. are not applicable):
      Not applicable
4. Clinical cut-off**:**
   Not determined
5. Expected values/Reference range:
   Concentrations of Beta-2-microglobulin in urine from healthy subjects averaged 0.098 mg/L with an upper normal limit of 0.32 mg/L (literature).

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 substantially equivalent decision.