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

A. 510(k) Number:
k050487

B. Purpose for Submission:
Clearance of a new device

C. Measurand:
Low-density lipoprotein

D. Type of Test:
Particle Enhanced Immunoturbidimetry

E. Applicant:
Bikit SA

F. Proprietary and Established Names:
Quantia Lp(a)
Quantia Lp(a) Control
Quantia Lp(a) standard

G. Regulatory Information:

1. Regulation section:
   21 CFR §866.5600, Low-density lipoprotein Immunological Test System
   21 CFR §866 862.1150, Calibrator
   21 CFR §862.1660, Quality Control Material (Assayed and Unassayed)

2. Classification:
   Class II; Class I (reserved)

3. Product code:
   DFC, Lipoprotein, Low-density
   JIS, Calibrator
   JJX, single (specified) Analyte Controls (Assayed and Unassayed)

4. Panel:
   Immunology (82)
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   The Quantia Lp(a) is intended as a latex particle enhanced immunturbidimetric

assay for the in vitro quantitative determination of lipoprotein (a) [Lp(a)] concentration in human serum or plasma (EDTA, heparin, citrate) on Clinical Chemistry Systems. The measurement of Lp(a) is useful in evaluating lipid metabolism disorders and assessing atherosclerotic cardiovascular disease in specific populations, when used in conjunction with clinical evaluation.

Quantia Lp(a) Control is intended for use in monitoring the quality control of results obtained with the Quantia Lp(a) reagents by turbidimetry.

Quantia Lp(a) standard is intended for use in establishing the calibration curve for the Quantia Lp(a) reagents by turbidimetry.

2. Indication(s) for use:
   See intended use above

3. Special conditions for use statement(s):
   For professional use only

4. Special instrument requirements:
   Clinical chemistry analyzers (performance characteristics determined using the AEROSET System)

I. Device Description:

The Quantia Lp(a) Latex Reagent is a suspension of polystyrene latex particles of uniform size coated with rabbit IgG anti-human Lp(a).

The Quantia Lp(a) Control (level I and II) and standard are prepared from human sera containing Lp(a) and sodium azide.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Dade Behring N-Latex Lp(a)

2. Predicate 510(k) number(s):
   K013128

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Quantitative in vitro diagnostic determination of Lp(a) .	Quantitative in vitro diagnostic determination of Lp(a) .
Analyte	Low-density lipoprotein	Low-density lipoprotein

Differences		
Item	Device	Predicate
Matrix	Serum and plasma (EDTA, heparin and citrate)	Serum and heparinized plasma

K. Standard/Guidance Document Referenced (if applicable):
CLSI Document EP5-A, EP6-A, EP7-A, and EP9-A2

L. Test Principle:
The Quantia Lp(a) Latex Reagent is a suspension of polystyrene latex particles of uniform size coated with rabbit IgG anti-human Lp(a). When a sample containing Lp(a) is mixed with the Latex Reagent and the reaction buffer included in the kit, a clear agglutination occurs. The degree of agglutination is directly proportional to the concentration of Lp(a) in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:
A precision study was performed on a AEROSET System using the Quantia Lp(a) Control I and II (low and high) run in duplicate twice a dayover twenty days (n=80). The within run, between run and total CV were calculated according to CLIS EP5-Aand summarized in following table.

Material	n	Mean (mg/dL)	Within Run CV (%)	Between Run CV (%)	Total CV(%)
Low	80	16.1	2.3	2.0	3.4
Medium	80	38.1	1.5	1.1	2.6
High	80	57.9	0.9	0.8	1.6

b. Linearity/assay reportable range:
Linearity was assessed according to CLSI EP6-A guideline.
1.28 to 90 mg/dL (2.0 to 204 nmol/L) without the automatic rerun capability
1.28 to 360 mg/dL (2.0 to 816 nmol/L) with the automatic rerun capability.
If after the automatic rerun the concentration of the sample exceeds the linearity range, dilute the sample 1:10 with saline solution, re-assay and multiply the result by the dilution factor of 10.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
The Quantia Lp(a) Control (level I and II) are prepared from human sera containing Lp(a), and sodium azide (< 0.1%). Refer to control value sheet for assigned values. Verify that the lot number listed on each bottle of the control agrees with the lot number printed on the value sheet. Reconstituted stability testing was performed to support the Quantia Lp(a) Control (low and high) of 15 days at 2-8^{0}C after reconstitution.

The calibrator is prepared from human sera containing Lp(a) and sodium azide < 0.1%. Calibration stability testing was performed using the Abbot Clinical Chemistry System AEROSET to support that calibration is stable for at least 30 days. Reconstituted stability testing was performed to support the Quantia Lp(a) Standard of 15 days at 2-8^{0}C after reconstitution.

c. *Detection limit:*
The detection limit was calculated by running thirty replicates of physiologic saline on an AEROSET System. The mean and standard deviation were calculated. The detection limit is defined as the mean reported value for the physiologic saline plus two standard deviations. The detection limit of this assay is 0.38 mg/dL.

d. *Analytical specificity:*
Interference testing was performed on an AEROSET System by spiking a sample containing Lipoprotein (a). For each interfering substance the sample was split in two aliquots, one being spiked with the concentrated interfering substance and the other with the control buffer (the buffer in which the interfering substance is dissolved). For this study , CLSI EP7-A was followed with the following results that no significant interference by:

Hemoglobin up to 460 mg/dL
Bilirubin up to 19.6 mg/dL
Triglycerides up to 1327 mg/dL
Turbidity of sample up to 2.3 AU/cm at 660 nm
Rheumatoid Factor up to 800 IU/ml

f. *Assay cut-off:*
Not applicable

2. Comparison studies:
   a. *Method comparison with predicate device:*
   Following CLSI EP9-A2, a comparative performance study was conducted by using 104 patient serum samples analyzed in duplicate with Quantia Lp(a) on an AEROSET System versus predicate, Dade Behring's N Latex Lp(a) on aBNII. The samples concentrations ranged from 2.4 to 188 mg/dL of Lp(a). The results from the study are summarized as following:
   Y = 1.121 x – 0.8; r = 0.9754; n = 104

Mathematical Method	Linear Regression
Slope	1.121
Intercept (mg/dL)	-0.8
Range (mg/dL)	2.4 – 188
Mean X (mg/dL)	44.8
Mean Y (mg/dL)	49.5
R	0.9754
Syx	10.76
N	104

b. Matrix comparison:
The plasma to serum correlation was generated with five sets of 50 paired samples on Hitachi – 917. Sodium EDTA plasma, potassium EDTA plasma, Lithium Heparin plasma, Sodium Heparin plasma and citrate plasma paired to serum samples used. The data from he studies show that results of the the paired serum and different plasma samples were equivalent.

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:
   Plasma Lipoprptein (a) concentration have been reported to be independent of body mass, age and sex. Concentrations of Lp(a) up to 30 mg/dL are considered normal.

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.