

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

A. 510(k) Number:

k040352

B. Analyte:

Total cholesterol, HDL cholesterol, LDL cholesterol, Apolipoprotein A-1,
Apolipoprotein B, triglycerides, C-reactive protein

C. Type of Test:

Quality control materials

D. Applicant:

Bioresource Technology Inc.

E. Proprietary and Established Names:

NOVA-ONE Lipid Control (Special Low Interference Liquid Lipid Control)

F. Regulatory Information:

1. Regulation section:
21 CFR §862.1660 Quality control material (assayed and unassayed)
2. Classification:
Class I
3. Product Code:
JJY
4. Panel:
75 – Clinical Chemistry

G. Intended Use:

1. Indication(s) for use:
“NOVA-One Control is intended for use in the laboratory to monitor the accuracy and precision of the listed constituents. The routine use of quality control materials is an integral part of evaluating the accuracy and precision of laboratory analysis.”
2. Special condition for use statement(s):
None described.
3. Special instrument Requirements:
This control is intended for use on the Cobras Mira, Abaxis Piccolo, Olympus AU5200/5400 and the Beckman Coulter Immage; not all components are tested by all instrument systems (see Expected Values below for table).

H. Device Description:

The device consists of two vials of liquid materials, Level 1(Normal) and Level 2 (Abnormal), prepared from human serum to which purified human proteins and chemicals have been added.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Medical Analysis Systems Liquid Assayed Lipid Control
2. Predicate K number(s):
k013734
3. Comparison with predicate:
Both products are two-level ready to use liquid controls. Both are based on human serum with various analytes added to adjust concentrations. They have an identical intended use, similar stability, and are used on identical or similar instrument systems. The nominal values of the individual analytes in each product are slightly different.

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

None listed.

K. Test Principle:

N/A

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
N/A
 - b. *Linearity/assay reportable range:*
N/A
 - c. *Traceability (controls, calibrators, or method):*
Value Assignment: On three days, three representative samples of the lot are assayed once for a specific component on its applicable instrument(s). The data is evaluated for gross outliers and a mean and standard deviation are calculated. The acceptance criterion for each method/analyte is a standard deviation of $\leq 15\%$.

Traceability: The instrument is calibrated with appropriate calibrators, and then a control from another manufacturer is run with the Bioresource control being tested. The sponsor did not provide traceability of the components to any international or internal reference standards.

Stability: The sponsor states that the product is stable for 2 years at -20°C , for 90 days at $2-8^{\circ}\text{C}$ when unopened, and for 30 days at $2-8^{\circ}\text{C}$ after opening. These claims are based on accelerated temperature

studies, where the acceptance criterion was $\pm 15\%$ of the zero time value.

d. *Detection limit:*

N/A

e. *Analytical specificity:*

N/A

f. *Assay cut-off:*

N/A

2. Comparison studies:

a. *Method comparison with predicate device:*

N/A

b. *Matrix comparison:*

N/A

3. Clinical studies:

a. *Clinical sensitivity:*

N/A

b. *Clinical specificity:*

N/A

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

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Representative Assigned Values for One Pilot Lot

Analyte (mg/L)	Instrument System	Level 1 (normal) (Lot 121603N)	Level 2 (abnormal) (Lot 031206A)
Total cholesterol			
	Cobas Mira	235	307
	Abaxis Piccolo	183	244
	Olympus AU5200/5400	194	253
HDL cholesterol			
	Cobas Mira	53	89
	Abaxis Piccolo	32	52
	Olympus AU5200/5400	41	62
LDL cholesterol			
	Cobas Mira	142	191
	Abaxis Piccolo	126	151
Triglycerides			
	Cobas Mira	129	198

	Abaxis Piccolo	142	217
	Olympus AU5200/5400	134	198
Apo A			
	Cobas Mira	148	267
Apo B			
	Cobas Mira	119	163
CRP			
	Beckman Coulter Immage	0.16	0.21

M. Conclusion:

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