

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

A. 510(k) Number:

k060850

B. Purpose for Submission:

Clearance to market quality control material.

C. Measurand:

Control material for ALT, albumin, ALP, amylase, AST, bilirubin- total and direct, BUN, calcium, CO₂, chloride, cholesterol (total, HDL, and LDL), CK, CK-MB, creatinine, CRP, fructosamine, GGT, glucose, iron, lactate, LDH, lipase, lithium, magnesium, phosphorus, potassium, sodium, total protein, triglycerides, and uric acid.

D. Type of Test:

Quality control material

E. Applicant:

Bioresource Technology, Inc.

F. Proprietary and Established Names:

NOD Chemistry Control

G. Regulatory Information:

1. Regulation section:

21CFR 862.1660, Quality control material (assayed and unassayed)

2. Classification:

Class I, reserved

3. Product code:

JJY, multi-analyte controls, all kinds (assayed and unassayed)

4. Panel:

(75) Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The NOD™ Chemistry Control is a two-level control set that is intended for in-vitro diagnostic use to monitor the precision of laboratory testing procedures for the analytes listed in the package insert (routine chemistries).

3. Special conditions for use statement(s):

For Prescription Use Only

4. Special instrument requirements:

Not applicable

I. Device Description:

The NOD™ Chemistry Control is a two-level control set that is prepared from purified human serum to which biochemical material (human and animal derived), drugs, chemicals, stabilizers, and preservatives have been added. Individual donor units used in the preparation of the controls were tested using FDA-cleared methods for anti-HIV-1 and 2, HBsAG, anti-HCV, HIV-1 antigens, and syphilis, and found to be non-reactive.

The controls are supplied in a pre-packaged liquid form to avoid potential error or contamination that could be introduced during reconstitution. The controls are tested in the same manner as clinical specimens, and therefore should be assayed according to the instructions accompanying the laboratory instrument, kit, or reagent system being used.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bio-Rad Multiquel® 1, 2, 3

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

k043208

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The NOD™ Chemistry Control is a two-level control set that is intended for in-vitro diagnostic use to monitor the precision of laboratory testing procedures for the analytes listed in the package insert	Same
Matrix	Prepared from human serum to which purified biochemical material (tissue extracts of human and animal origin), chemicals, drugs, preservatives, and stabilizers have been added.	Same
Form	Liquid, ready-to-use	Same

Differences		
Item	Device	Predicate
Analytes	ALT, albumin, ALP, amylase, AST, bilirubin-total and direct, BUN, calcium, CO2, chloride, cholesterol- total, HDL, and LDL, CK, CK-MB, creatinine, CRP, fructosamine, GGT, glucose, iron, lactate, LDH, lipase, lithium, magnesium, phosphorus, potassium, sodium, total protein, triglycerides, and uric acid	Additional analytes
Stability(unopened storage claim)	30 days when stored tightly capped at 2-8°C	Not all analytes are stable for 30 days

Differences		
Item	Device	Predicate
Stability(opened vial claim)	14 days when stored tightly capped at 2-8°C	Not all analytes are stable for 14 days

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

None referenced.

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not Applicable for a submission of this type.

b. *Linearity/assay reportable range:*

Not Applicable for a submission of this type.

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

The company assigns values to their controls by assaying 6 randomly selected vials from each manufacturing lot. Vials are measured in triplicate and measured across 3 instruments.

The company assessed the stability of their product through real-time aging studies. Vials were randomly selected from a manufacturing lot and stored at the designated aging temperature. Samples were periodically withdrawn for concentration measurements.

As an example, for sealed samples stored at 4 °C, the company demonstrated:

Analyte	Initial Concentration	Concentration at 35 days	Percent Change	Concentration Range Accepted by Company
Albumin	5.5 g/dl	5.4 g/dl	1.82%	4.5 - 6.7
Alkaline Phosphatase	430 U/L	446 U/L	-3.72%	345 – 517
ALT	217 U/L	211 U/L	2.76%	184 – 275
Amylase	390 U/L	393 U/L	-0.77%	312 – 468
AST	134 U/L	127 U/L	5.22%	98 – 146

Analyte	Initial Concentration	Concentration at 35 days	Percent Change	Concentration Range Accepted by Company
Bilirubin-total	3.3 mg/dl	3 mg/dl	9.09%	2.4 - 3.6
Calcium-total	11.5 mg/dl	11.2 mg/dl	2.61%	10.0 - 15.0
Chloride	121 mEq/L	121 mEq/L	0.00%	96 - 144
LD	187 U/L	191 U/L	-2.14%	149 - 225
CK	771 U/L	788 U/L	-2.20%	616 - 926
Creatinine	1.5 mg/dl	1.5 mg/dl	0.00%	1.3 - 1.9
GGT	79 U/L	75 U/L	5.06%	63 - 95
Glucose	177 mg/dl	181 mg/dl	-2.26%	138 - 206
Magnesium	3 mg/dl	2.9 mg/dl	3.33%	2.5 - 3.7
Phosphorus	5.7 mg/dl	5.9 mg/dl	-3.51%	5.0 - 7.4
Potassium	4.9 mEq/L	4.9 mEq/L	0.00%	4.5 - 6.7
Protein-total	8.9 g/dl	8.8 g/dl	1.12%	7.0 - 10.6
Sodium	166 mEq/L	168 mEq/L	-1.20%	136 - 204
Urea Nitrogen	39 mg/dl	41 mg/dl	-5.13%	31 - 47
Uric Acid	6.9 mg/dl	7 mg/dl	-1.45%	5.6 - 8.4
Cholesterol	256 mg/dl	263 mg/dl	-2.73%	205 - 307
HDL	61 mg/dl	59 mg/dl	3.28%	52 - 78
Triglycerides	241 mg/dl	254 mg/dl	-5.39%	187 - 281

The data supplied by the company substantiates their claim for a 28 day shelf life when stored unopened at 2 – 8 °C.

The company substantiated their claim for an opened, capped and refrigerated shelf life using real-time aging studies done at 4 °C. A summary of their findings for one example:

Analyte	Initial Concentration	Concentration at 14 days	Percent Change	Concentration Range Accepted by Company
Albumin	5.5 g/dl	5.5 g/dl	0.00%	4.5 - 6.7
Alkaline Phosphatase	430 U/L	443 U/L	-3.02%	345 - 517
ALT	217 U/L	214 U/L	1.38%	184 - 275
Amylase	390 U/L	390 U/L	0.00%	312 - 468
AST	134 U/L	133 U/L	0.75%	98 - 146
Bilirubin-total	3.3 mg/dl	3.3 mg/dl	0.00%	2.4 - 3.6
Calcium-total	11.5 mg/dl	11.2 mg/dl	2.61%	10.0 - 15.0
Chloride	121 mEq/L	121 mEq/L	0.00%	96 - 144
LD	187 U/L	190 U/L	-1.60%	149 - 225
CK	771 U/L	792 U/L	-2.72%	616 - 926
Creatinine	1.5 mg/dl	1.5 mg/dl	0.00%	1.3 - 1.9
GGT	79 U/L	80 U/L	-1.27%	63 - 95
Glucose	177 mg/dl	184 mg/dl	-3.95%	138 - 206
Magnesium	3 mg/dl	2.8 mg/dl	6.67%	2.5 - 3.7
Phosphorus	5.7 mg/dl	5.9 mg/dl	-3.51%	5.0 - 7.4
Potassium	4.9 mEq/L	4.9 mEq/L	0.00%	4.5 - 6.7
Protein-total	8.9 g/dl	8.7 g/dl	2.25%	7.0 - 10.6

Analyte	Initial Concentration	Concentration at 14 days	Percent Change	Concentration Range Accepted by Company
Sodium	166 mEq/L	166 mEq/L	0.00%	136 - 204
Urea Nitrogen	39 mg/dl	39 mg/dl	0.00%	31 - 47
Uric Acid	6.9 mg/dl	6.8 mg/dl	1.45%	5.6 - 8.4
Cholesterol	256 mg/dl	248 mg/dl	3.13%	205 - 307
HDL	61 mg/dl	64 mg/dl	-4.92%	52 - 78
Triglycerides	241 mg/dl	242 mg/dl	-0.41%	187 - 281

The data supplied by the company substantiates their claim for a 14 day shelf life when stored opened but capped at 2 – 8 °C.

d. Detection limit:

Not applicable for a device of this type.

e. Analytical specificity:

Not applicable for a device of this type.

f. Assay cut-off:

Not applicable for a device of this type.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable for a device of this type.

b. Matrix comparison:

Not applicable for a device of this type.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable for a device of this type.

b. Clinical specificity:

Not applicable for a device of this type.

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

Not applicable for a device of this type.

4. Clinical cut-off:

Not applicable for a device of this type.

5. Expected values/Reference range:

Not applicable for a device of this type.

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.