

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

A. 510(k) Number:

K032453

B. Analytes:

Controls for the measurement of pH, blood gases, Na⁺, K⁺, Cl⁻, iCa⁺⁺, tHb and Hb derivatives, glucose, Urea/BUN, lactate, and bilirubin

C. Type of Test:

N/A (controls only)

D. Applicant:

Bionostics, Inc.

E. Proprietary and Established Names:

Roche COMBITROL PLUS B and Roche AUTOTROL PLUS B Multi Analyte Controls

F. Regulatory Information:

1. Regulation section:
CFR 862.1660
2. Classification:
Class I
3. Product Code:
JJY
4. Panel:
Clinical Chemistry (75)

G. Intended Use:

1. Indication(s) for use:
COMBITROL PLUS B / AUTOTROL PLUS B assayed controls are intended to be used to monitor and evaluate the analytical performance of the Roche OMNI S for analytes listed in the package insert.
2. Special condition for use statement(s):
Prescription Use Only
3. Special instrument Requirements:
Roche OMNI S

H. Device Description:

The COMBITROL PLUS B / AUTOTROL PLUS B assayed controls consist of three levels of a non-hazardous aqueous-based solution and are to be used to monitor the performance of the Roche OMNI S analyzer only. The contents of the COMBITROL PLUS B and AUTOTROL PLUS B assayed controls are identical. The AUTOTROL PLUS B control is designed to work with the optional Auto QC module, while the COMBITROL PLUS B is designed for analyzers without this option.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Blood Gas, Electrolyte, and CO-Oximetry Control; Blood Gas, Electrolyte, Metabolite Control

2. Predicate K number(s):
K913133; K972868
3. Comparison with predicate:

Similarities			
Item	Device	Predicate 1	Predicate 2
Name	Roche COMBITROL PLUS B / AUTOTROL PLUS B	Blood Gas, Electrolyte, and CO-Oximetry Control	Blood Gas, Electrolyte, Metabolite Control
510(k) Number	K032453	K913133	K972868
No. of Levels	3	3	3
Analytes	pH, blood gases, Na ⁺ , K ⁺ , Cl ⁻ , iCa ⁺⁺ , tHb and Hb derivatives, glucose, Urea/BUN, lactate, and bilirubin	pH, blood gases, Na ⁺ , K ⁺ , Cl ⁻ , iCa ⁺⁺ , tHb and Hb derivatives	pH, blood gases, Na ⁺ , K ⁺ , Li ⁺ , Cl ⁻ , iMg ⁺⁺ , iCa ⁺⁺ , glucose, lactate, BUN, creatinine
Container	Clear, glass ampoule	Clear, glass ampoule	Clear, glass ampoule
Matrix	Buffered, aqueous electrolyte solution equilibrated with carbon dioxide and oxygen gas mixture	Buffered, aqueous electrolyte solution equilibrated with carbon dioxide and oxygen gas mixture	Buffered, aqueous electrolyte solution equilibrated with carbon dioxide and oxygen gas mixture
Differences			
Item	Device	Predicate 1	Predicate 2
Color	Red	Red	Clear
Fill volume	1.7 mL	2.5 mL	2.5 mL

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

N/A

K. Test Principle:

N/A

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The 17 analytes contained in these controls were analyzed on a Roche OMNI S analyzer according to NCCLS Evaluation Protocol EP-05. Coefficients of variation ranged from <1 to 5.6%.

b. *Linearity/assay reportable range:*

N/A

c. *Traceability (controls, calibrators, or method):*

In – house reference lot

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):
4. Clinical cut-off:
N/A
5. Expected values/Reference range:
N/A

M. Conclusion:

Based upon the information provided for the file, I recommend that the Roche COMBITROL PLUS B and AUTOTROL PLUS B Multi Analyte Controls are substantially equivalent to the predicate devices.