

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

A. 510(k) Number:

k070504

B. Purpose For Submission:

Premarket Notification 510(k) of intention to manufacture and market the Pointe Scientific, Inc. Ammonia/Alcohol Control Set.

C. Analyte:

Not Applicable - Ammonia/Alcohol Control Set.

D. Type of Test:

Quality Control Material

E. Applicant:

Pointe Scientific, Inc.

F. Proprietary and Established Names:

Pointe Scientific, Inc. Ammonia/Alcohol Control Set

G. 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

H. Intended Use:

1. Intended use(s):

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

The Pointe Scientific, Inc. Ammonia/ Alcohol Control Set is to be used for monitoring the accuracy and precision of various ammonia and/ or ethanol assay methods and to validate quantitation of patient samples. The controls contain components of known concentrations and are an integral part of diagnostic procedures. Daily monitoring of control values establishes intralaboratory parameters for accuracy and precision of the test method.

3. Special condition for use statement(s):

Prescription use.

4. Special instrument Requirements:

Values are listed for Roche Cobas Mira Plus

I. Device Description:

The Pointe Scientific, Inc. control material is supplied as a two level control set, 2 x 5 ml, as a ready-to-use liquid requiring no reconstitution or dilution. It is prepared in an aqueous base fortified with ethanol and reagent grade chemicals. Preservatives have been added to inhibit microbial growth.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Quantimetrix Ammonia/ Alcohol Control

2. Predicate K number(s):

k913346

3. Comparison with Predicate:

The Pointe Scientific Ammonia/ Alcohol Control Set were compared to the previously cleared Quantimetrix Ammonia/ Alcohol Control 510(k) k913346. The table below lists the similarities and differences between the Predicate and Proposed device.

Pointe Scientific, Inc. Ammonia/ Alcohol Control Set (k070504)	Quantimetrix Ammonia/ Alcohol Control (k913346)
Two Level Control	Three Level Control
Aqueous based	Bovine Albumin based
Ethanol	Ethanol
Reagent grade Chemicals	Reagent grade Chemicals
Preservatives	Preservatives

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

b. *Linearity/assay reportable range:*

Not Applicable

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

The sponsor claims traceability of the Pointe Scientific, Inc. Ammonia/Alcohol Control Set to the following source: Alcohol traceability – NIST SRM# 1828b and Ammonia traceability – ACS Reagent Grade Ammonium Chloride (no current NIDT SRM available).

Value assignment runs were calibrated with products traceable to material stated above. A minimum of three runs, per analyzer, per level were performed generating 6-10 values per run. As many as four different analyzers were used in the process. Mean values were determined from this data for each analyzer system.

The sponsor demonstrated through closed shelf life stability studies that the Pointe Scientific Ammonia/ Alcohol Control Set demonstrated a shelf life of 12 months. Open vial stability studies were also conducted by the sponsor indicating a 20 day stability at 2-8° C. The sponsor's stability study support that the Pointe Scientific, Inc. Ammonia/Alcohol Control Set is stable up to 12 months unopened and 20 days opened at 2-8° C.

d. *Detection limit:*

Not Applicable

e. *Analytical specificity:*

Not Applicable

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not Applicable

b. Matrix comparison:

Not Applicable

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:

Not Applicable

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.