

SEP 13 1996

K962629

Exhibit 21. 510(k) Summary

FEDERAL FOOD, DRUG AND COSMETIC ACT
510(k) SUMMARY

DOCUMENT[®] Ammonia, Ethanol, Lactate Calibrator, Levels I, II, III

1. Submitted by: CASCO Standards
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2. Product Name:

Proprietary Name: **DOCUMENT[®] Ammonia, Ethanol, Lactate Calibrator**

Classification Name: Control, multiple analyte, assayed.

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3. Predicate Device:

Analyte: Ammonia

Manufacturer: Boehringer Mannheim Corp., Indianapolis, IN

System: Hitachi 717 System

Reagents: Boehringer Mannheim Corp., Ammonia, Kit No. 450055

Calibrator: New England Reagent Laboratories, East Providence, RI
Ammonia Standards, 100µmol/L , part of Kit No. NERL 1207

Analyte: Ethanol

Manufacturer: Beckman Instruments, Brea, CA

System: Beckman Synchron CX5

Reagents: Beckman Instruments, Alcohol, Kit No: 445900

Calibrator: Beckman Instruments, Fullerton, CA
Alcohol, part of Kit No. 445900

Analyte: Lactate

Manufacturer: Beckman Instruments, Brea, CA

System: Beckman Synchron CX5

Reagents: Beckman Instruments, Lactate, Kit No. 445875

Calibrator: Beckman Instruments, Fullerton, CA
Lactate, CX Multi Calibrator, Part No. 442600

4. Product Description: **DOCUMENT Ammonia, Ethanol, Lactate Calibrators** consist of one level of an aqueous matrix containing ammonia, ethanol, and lactate. The formulation design provides a liquid calibrator intended for use on automated, semi-automated, and manual clinical chemistry systems for the quantitative determination of ammonia (AMM), ethanol (ALC) and lactate (LAC).

5. Intended Use: **DOCUMENT Ammonia, Ethanol, Lactate Calibrator** is intended for *in vitro* diagnostic use for the quantitative calibration of automated, semi-automated, or manual clinical chemistry systems used for the measurement of ammonia, ethanol, and lactate. **DOCUMENT Ammonia, Ethanol, Lactate Calibrator** is intended to provide for the quantitative calibration of automated, semi-automated, and manual clinical chemistry systems. Each lot of **DOCUMENT Ammonia, Ethanol, Lactate Calibrator** has lot specific calibration set point values included for the various analytical systems on which it was assayed.

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6. Comparison to the Predicate Device:

Characteristic	DOCUMENT Ammonia, Ethanol, Lactate Calibrator	New England Reagent Laboratory Ammonia Standards	Beckman Alcohol Kit Calibrator	Beckman CX Multi Calibrator
Intended Use	Intended for the quantitative calibration of automated, semi-automated, and manual clinical chemistry systems.	None given	Intended for the quantitative determination of alcohol concentration in serum or plasma on SYNCHRON CX Systems	Intended for use on the SYNCHRON CX Systems for the calibration of, Lactate, ...
Number of Levels	One	Five	One	One
Type	Traceable: Ammonia Ethanol Assigned: Lactate	Assigned	Assigned	Assigned
Analytes	3	1	1	Many
Volume	4 mL	5 mL	5 mL	20 mL
Matrix	Aqueous	Aqueous	Aqueous	Human serum, Liquid
Dilution	None required	None required	None required	None required
Unopened Stability	Until Expiration Date	Until Expiration Date	Until Expiration Date	Until Expiration Date
Open Stability	30 Days	None indicated	7 Days	20 Days
Container	Plastic, Dropper Tip	Plastic, Dropper Tip	Plastic, Dropper Tip	Plastic, Dropper Tip

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7. Test Results:

The equivalence for this product was carried out by comparing quantitative analytical recovery of patient samples using the NCCLS EP9 Protocol: *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline*. The **DOCUMENT Ammonia, Ethanol, Lactate Calibrator** was compared to the NERL 100 μ mol/L Ammonia Standard using BMC Ammonia reagents on a Hitachi 717 Clinical Chemistry Analyzer, the Beckman Alcohol Kit Calibrator with Beckman Reagents on a Beckman Synchron CX5 System, and the Beckman CX Multi Calibrator using Beckman Lactate reagent on a Beckman Synchron CX5 System. The results show that the **DOCUMENT Ammonia, Ethanol, Lactate Calibrator** behaves in a similar manner compared to the predicate devices and is suitable for use as a calibrator for the listed analytes on those systems tested.