

**K963543**

**510(k) NOTIFICATION**

**Sigma Diagnostics  
545 South Ewing Avenue  
St. Louis, MO 63103**

**CX<sup>®</sup>-3 Calibration Standard, Level 2  
Procedure No. C7433  
August 30, 1996**

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**OCT 30 1996**

**ATTACHMENT 1**

**Summary of Safety and Effectiveness**

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### SUMMARY OF SAFETY AND EFFECTIVENESS

Sigma Diagnostics CX<sup>3</sup> Calibration Standard Level 2 is used to calibrate the Beckman SYNCHRON CX<sup>3</sup> System. This reagent is used for the quantitative determination of BUN/urea, calcium, and total carbon dioxide in serum or plasma; of creatinine, potassium, and sodium in serum, plasma, or urine; and of chloride and glucose in serum, plasma, urine, or cerebrospinal fluid. Calibration Standard Level 2 should be used with CX<sup>3</sup> Calibration Standard Level 1.

CX<sup>3</sup> Calibration Standard Level 2 contains the following analytes and other non-reactive components:

<b>ANALYTE</b>	<b>SI UNITS</b>
Chloride	65 mmol/L
Potassium	10.0 mmol/L
Sodium	100 mmol/L
Total CO <sub>2</sub>	30 mmol/L

The safety and effectiveness of Sigma Diagnostics CX<sup>3</sup> Calibration Standard, Level 2, Procedure Number C7433, are demonstrated by its substantial equivalency to Beckman Calibration Standard 2, Part No. 443365.