

K963536

510(k) NOTIFICATION

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

**CX[®]-3 Calcium Reagent
Procedure No. C7183
August 30, 1996**

OCT 10 1996

ATTACHMENT 1

Summary of Safety and Effectiveness

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CX³ Calcium Reagent
Procedure Number C7183
August 31, 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

The concentration of calcium is determined by the balance between absorption in the intestine and excretion in the kidneys and by exchanges between plasma, extracellular fluid and tissues including bone. Diseases associated with hypercalcemia include primary hyperthyroidism and hypercalcemia of malignancy. Hypocalcemia is associated with hypoparathyroidism and pseudohypoparathyroidism, vitamin D deficiency, hereditary vitamin D dependency, rickets types I and II, and intestinal malabsorption.¹

Many methods exist for determining calcium. The o-cresolphthalein complexone method remains popular in the clinical laboratory because performing it is fast and easy.

The arsenazoIII method is a relatively new single reagent method. It is rapidly gaining popularity because it is even easier to use and has virtually no magnesium interference even at levels as high as 20 mg/dL.² Further modifications to the method, in conjunction with sample blanking on the SYNCHRON CX³ System, have resulted in a rapid calcium test with increased specificity.

The safety and effectiveness of Sigma Diagnostics Calcium Reagent, Procedure Number C7183, are demonstrated by its substantial equivalency to Beckman Calcium Reagent Kit, Part No. 450890. Both calcium reagents are used to measure calcium concentrations in serum, plasma, or urine on the SYNCHRON CX³ System, and the reaction principles for both are identical. In comparison studies, a correlation coefficient of 0.982 and a regression equation of $y = 0.95x + 0.54$ was obtained with serum samples; and a correlation coefficient of 0.996 and a regression equation of $y = 1.02x - 0.15$ was obtained with urine samples. With-in run precision and total precision demonstrated %CV's of less than 2.4 % on serum samples and less than 1.5 % on urine samples. The Sigma Diagnostics Calcium Reagent has been determined to be linear to 15.5 mg/dL on the SYNCHRON CX³ System.

REFERENCES

1. Textbook of Clinical Chemistry, N Tietz, Editor, WB Saunders, Co, Philadelphia, PA, 1986
2. Schmitz J, et al: Clin Chem 32: 1198, 1986