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510(K) NOTIFICATION

Sigma Diagnostics
545 South Ewing Avenue
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CX[®]3 Creatinine Reagent Set
Procedure Number C7058
August 31, 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

Creatinine is synthesized in the kidney, the liver, and the pancreas.¹ It is transported in the blood to other organs such as muscle and brain where it is phosphorylated to phosphocreatine. Some free creatine in muscle is converted to creatinine daily, and the amount of creatinine produced is proportional to muscle mass. In the absence of renal disease, the excretion rate of creatinine in an individual is relatively constant. Therefore, measurement of creatinine clearance is useful in detecting renal disease and estimating the extent of impairment of renal function.²

Most methods for creatinine measurement are based on the Jaffe reaction, where yellow/orange color forms when the metabolite is treated with alkaline picrate.³ The Sigma Diagnostics Creatinine Reagent Set for the SYNCHRON CX[®]3 is formulated based on a modification of the Jaffe reagents described by Heinegard and Tiderstrom. These modifications minimize the effect of interfering substances.⁴

The safety and effectiveness of Sigma Diagnostics Creatinine Reagent Set, Procedure Number C7058, is demonstrated by its substantial equivalency to Beckman Creatinine Reagent Kit, Part No. 443340. Both creatinine reagents are used to measure creatinines concentrations in serum, plasma, or urine on the SYNCHRON CX[®]3 System, and the reaction principles for both reagents are identical. In comparison studies, a correlation coefficient of 0.999 and a regression equation of $y = 1.03x - 0.01$ was obtained with serum samples; and a correlation coefficient of 0.998 and a regression equation of $y = 0.99x + 0.21$ was obtained with urine samples. With-in run precision and total precision demonstrated %CV's of less than 4.5 % on serum samples and less than 2.1 % on urine samples. The Sigma Diagnostics Creatinine Reagent has been determined to be linear to 25 mg/dL with serum samples, and from 10 to 400 mg/dL with urine samples on the SYNCHRON CX[®]3 System.

REFERENCES:

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3. Jaffe M: Ueber den Niederschlag, welchen Picrinsaure in narmalen Harm eraeugt und uber eine neue Reaction des Kreatinins. Hoppe Seylers Z Physiol Chem 10:391, 1886
4. Tietz, NW, Clinical Guide to Laboratory Tests, WB Saunders, Co, Philadelphia, 1983