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510(K) NOTIFICATION

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Sigma Diagnostics
545 South Ewing Avenue
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CX[®]3 BUN Reagent
Procedure Number B1657
August 31, 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

The level of blood urea nitrogen (BUN) is regulated by the metabolism of proteins and by the renal excretion of urea.¹ BUN determination, therefore, has become the most widely used screening procedure for evaluating kidney function. Increased BUN levels occur in cases of impaired kidney function such as chronic nephritis, acute glomerulonephritis, polycystic disease of the kidney, nephrosclerosis and tubular necrosis.² BUN levels are also elevated due to urinary tract obstruction and during the terminal stage of liver disease. Decrease in BUN levels often accompany primary hepatic insufficiency and acute hepatitis.

In 1961, Chin and Kroontje reported a method for determining urea based upon the difference in conductivity of urea and the ammonium bicarbonate produced by urease from urea.³ In 1971, the method was modified to detect urea by measuring the rate of increase of conductivity.⁴ The Sigma Diagnostics BUN Reagent is formulated to use this methodology on the SYNCHRON CX[®]3 System.

The safety and effectiveness of Sigma Diagnostics BUN Reagent, Procedure Number B1657, are demonstrated by its substantial equivalency to Beckman BUN Reagent Kit, Part No. 443350. Both reagents are used to measure BUN concentrations in serum or plasma on the SYNCHRON CX[®]3 System, and the reaction principles for both are identical. In a comparison study, a correlation coefficient of 0.999 and a regression equation of $y = 1.03x - 0.19$ was obtained with serum samples. Within run precision and total precision on serum samples demonstrated %CV's of less than 4%. The Sigma Diagnostics BUN Reagent has been determined to be linear to 125 mg/dL.

REFERENCES

1. Cantarow A, Trumper M: Clinical Biochemistry, WB Saunders Company, Philadelphia, 1975, pp 207-209
2. Tietz NW: Fundamentals of Clinical Chemistry, WB Saunders Company, Philadelphia, 1976, p 993
3. Textbook of Clinical Chemistry, NW Tietz, Editor, WB Saunders Company, Philadelphia, 1986
4. Chin WT, Kroontje W: Anal Chem 33:1757, 1961