

K963142

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510(k) SAFETY AND EFFECTIVENESS SUMMARY

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Submitter: Bayer Corporation, Business Group Diagnostics

Address: 1884 Miles Avenue, P. O. Box 70
Elkhart, IN 46515
(219) 262-6929

Contact: Rosanne M. Savol, R.A.C.
Manager, Regulatory Affairs

Device: Trade/Proprietary Name: DCA 2000®+ Microalbumin/Creatinine Assay
Common/Usual Name: Test for microalbumin in urine
Test for creatinine in urine
Document Control Number: K96_____

Classification Division of Clinical Laboratory Devices
Panel - Clinical Chemistry and Toxicology
Classification Code - 75 JIR (Urinary Protein or Albumin)
75 CGX (Alkaline Picrate, Colorimetry, Creatinine)

Predicate Devices: Incstar® Antibody Reagent Set for Microalbumin SPQ™ Test System; Diagnostic Products Corporation Double Antibody Albumin RIA for microalbuminuria; Pharmacia Albumin RIA; Behring Turbitimer semiautomated method for albumin; Beckman Array® nephelometric method for albumin; Roche® Reagent for CREATININE [Roche Cobas™-Mira]; automated Jaffe methods for Hitachi, Olympus and Dupont Dimension analyzers; Sigma manual alkaline picrate method

Device Description: The DCA 2000+ Microalbumin/Creatinine Assay is a convenient, quantitative method for measuring low concentrations of albumin (microalbumin), creatinine and albumin/creatinine ratio in urine. The DCA 2000+ Microalbumin/Creatinine Assay is designed to be used with the DCA 2000+ Analyzer and the

DCA 2000+ Microalbumin/Creatinine Control Kit. It is self-contained reagent/instrument system that is suitable for use in decentralized, or point-of-care laboratories such as physician office laboratories, clinics and hospitals.

Intended Use: The DCA 2000+ Microalbumin/Creatinine Assay is a professional use device for the measurement of microalbumin, creatinine and albumin/creatinine ratio in urine. Testing for microalbuminuria (low concentrations of albumin in the urine) is recommended in patients with insulin-dependent diabetes mellitus (IDDM) as well as patients with non-insulin dependent diabetes mellitus (NIDDM). This assay is intended for use in both screening for, and monitoring treatment of, microalbuminuria.

Technological Characteristics:

The DCA 2000+ Microalbumin/Creatinine Assay employs an immunoassay for the microalbumin test and an alkaline, colorimetric assay for the creatinine test. The reagents are contained in a reagent cartridge. The DCA 2000+ Analyzer controls the reaction steps and automatically performs all the measurements and calculations. Results are displayed on the instrument screen. The system is factory calibrated.

Assessment of Performance:

The performance of the DCA 2000+ Microalbumin/Creatinine Assay was studied in clinical settings by typical users of the system and results compared to currently used tests for microalbumin and creatinine. The studies demonstrated that typical users in decentralized, point-of-care laboratories can obtain clinical test results that are substantially equivalent to current methods.

Conclusion:

The DCA 2000+ Microalbumin/Creatinine Assay is a convenient method for measuring microalbumin and creatinine in urine. Studies show that it can be used in decentralized and point-of-care laboratories and provide clinical results comparable to other test methods in current clinical laboratory practice.