K992800

SEP 28 1999

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

INFINITY™ BUN Reagent, Procedure 63

Sigma Diagnostics INFINITY™ BUN Reagent is intended for the in vitro quantitative, diagnostic determination of Urea (or Urea Nitrogen) in human serum, plasma or urine on both automated and manual systems.

Urea is the major end product of protein nitrogen metabolism in humans. It constitutes the largest fraction of the non-protein nitrogen component of the blood. Urea is produced in the liver and excreted through the kidneys in the urine. Consequently, the circulating levels of urea depend upon protein intake, protein catabolism and kidney function. Elevated urea levels can occur with dietary changes, diseases which impair kidney function, liver diseases, congestive heart failure, diabetes, and infections.

The enzyme methodology employed in this reagent is based on the reaction first described by Talke and Schubert.[2] To shorten and simplify the assay, the calculations are based on the discovery of Tiffany, et al.[3] that urea concentration is proportional to absorbance change over a fixed time interval.

The series of reactions involved in the assay system is as follows:

1. Urea is hydrolyzed in the presence of water and urease to produce ammonia and carbon dioxide.

   $$\text{Urea} + H_2O \xrightarrow{\text{Urease}} 2NH_3 + CO_2$$

2. In the presence of glutamate dehydrogenase (GLDH) and reduced nicotinamide adenine dinucleotide (NADH), the ammonia combines with α-ketoglutarate (α-KG) to produce L-glutamate.

   $$NH_3 + \alpha\text{-KG} + \text{NADH} \xrightarrow{\text{GLDH}} \text{L-Glutamate} + \text{NAD}$$

INFINITY BUN reagent has the convenience of being a single vial reagent and also incorporates a patented dynamic stabilization process which regenerates NADH from NAD (oxidized NADH), thereby increasing the shelf life of the reagent.

The Sigma Diagnostics INFINITY™ BUN Reagent (Procedure No. 63) is substantially equivalent to, and is the same product as the TRACE Scientific BUN Reagent kit cleared by the FDA as K971477.

Correlation studies to Sigma Diagnostics BUN Reagent, Procedure No. 67 (K863196) using plasma samples yielded a regression equation of:

INFINITY BUN = 0.95 (BUN 63) + 1.1 (N=126)

References

1. Tietz Textbook of Clinical Chemistry. Burtis CA and Ashwood ER (Eds). Second Edition. WB Saunders Company, 1994
2. Talke H, Schubert GE. Klin Wochschr 19; 43:174
3. Tiffany TO, Jansen JM, Burtis CA, Overton JB, Scott CD. Clin Chem 18:829-40, 1972

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 8 1999

William R. Gilbert, Ph.D.
Manager, Scientific Affairs
Sigma Diagnostics®
Clinical Technical Services
545 South Ewing Avenue
St. Louis, Missouri 63103

Re: K992800
Trade Name: Infinity™ BUN Reagent (Procedure No. 63)
Regulatory Class: II
Product Code: CDQ
Dated: August 16, 1999
Received: August 19, 1999

Dear Dr. Gilbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992800

Device Name: INFINITY™ BUN Reagent

Indications For Use:

The Sigma Diagnostics INFINITY™ BUN Reagent is a device intended to measure urea nitrogen (an end product of nitrogen metabolism) in serum, plasma or urine. Measurements obtained by the device are used in the diagnosis and treatment of certain renal and metabolic diseases.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992800

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR **Over-The-Counter Use** ___
(Per 21 CFR 801.109)