

K982251

AUG 18 1998

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

INFINITY™ Uric Acid Reagent, Procedure 684

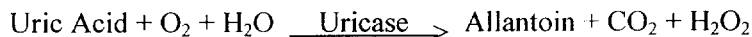
Sigma Diagnostics INFINITY™ Uric Acid Reagent is intended for the in vitro quantitative, diagnostic determination of uric acid in human serum or urine on both automated and manual systems.

Uric acid is a metabolite of purines, nucleic acids and nucleoproteins. Consequently, abnormal levels may be indicative of a disorder in the metabolism of these substances. Hyperuricaemia may be observed in renal dysfunction, gout, leukemia, polycythaemia, atherosclerosis, diabetes, hypothyroidism, or in some genetic diseases. Decreased levels are present in patients with Wilson's Disease.<sup>1-3</sup>

This reagent is based upon the methods of Trivedi and Kabasakallan<sup>4,5</sup> with a modified Trinder<sup>6</sup> peroxide assay using 2,4,6-Tribromo-3-hydroxy benzoic acid (TBHB).

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

1. Uric Acid is oxidized to allantoin by uricase with the production of H<sub>2</sub>O<sub>2</sub>.



2. The peroxide reacts with 4-aminoantipyrine (4-AAP) and TBHB in the presence of peroxidase to yield a quinoneimine dye. The resulting change in absorbance at 520 nm (500-550 nm) is proportional to uric acid concentration in the sample.



The Sigma Diagnostics INFINITY™ Uric Acid Reagent (Procedure No. 684) is substantially equivalent to, and is the same product as the TRACE Scientific Uric Acid Reagent kit cleared by the FDA as K971485.

### References

1. Searcy RL: Diagnostic Biochemistry. McGraw-Hill, New York, NY, 1969
2. Henry RJ, Common C, Winkelman JW (eds), Clinical Chemistry: Principles and Techniques. Harper & Row, Hagerstown, MD, 1974
3. Balls ME: Adv Clin Chem 18:213, 1976
4. Trivedi R, Berta E, Rebar L: Clin Chem, 22:1223, 1976
5. Kabasakallan P, Kalliney S, Wescott A: Clin Chem, 19:522, 1973
6. Trinder P: J Clin Pathol, 22:246, 1949



AUG 18 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

William Gilbert, Ph.D.  
Manager, Scientific Affairs  
Sigma Diagnostics Inc.  
545 South Ewing Avenue  
St. Louis, Missouri 63103

Re: K982251  
INFINITY™ Uric Acid Reagent (Procedure No. 684)  
Regulatory Class: I  
Product Code: CDO  
Dated: June 23, 1998  
Received: June 26, 1998

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 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 (Pre-market 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 pre-market 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.

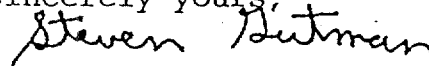
Page 2

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/dsmamain.html>".

Sincerely yours,



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): \_\_\_\_\_

Device Name: INFINITY™ Uric Acid Reagent

**Indications For Use:**

The Sigma Diagnostics INFINITY™ Uric Acid Reagent is a device intended to measure uric acid in serum. Measurements obtained by the device are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

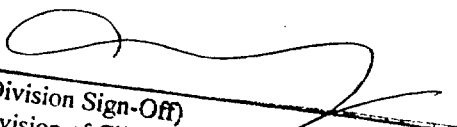
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use**   
(Per 21 CFR 801.109)

OR

**Over-The-Counter Use**

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices

510(k) Number K982251