

K971886

510(k) Notification  
Unotech Diagnostics Inc.  
AccuTest™ hCG-Urine  
May 21, 1997

**510(k) Summary of Safety and Effectiveness  
Substantial Equivalence Discussion**

Trade or Proprietary Name: AccuTest™ hCG-Urine  
Common or Usual Name: Human Chorionic Gonadotropin Test System  
Product Classification No.: 21 CFR §862.1155, Class II  
Manufacturer: Unotech Diagnostics Inc.  
2235 Polvorosa Avenue, Suite 220  
San Leandro, CA 94577  
Contact Person: Ken Wu, Ph.D.  
President  
Phone: (510) 352-3070

We conducted a multicenter clinical study in three physicians' offices laboratories. We provided each site with the Unotech AccuTest™ hCG-Urine and the Abbott TestPack Plus™ hCG-COMBO.

A total of 197 urine specimens were tested in these physicians' offices laboratories using both Unotech and Abbott tests. Clinical subjects included female patients seeking confirmation of pregnancy, those who were confirmed pregnant, and 8 post-menopausal women.

The test results show that the Unotech AccuTest™ hCG-Urine has 100% agreement with the Abbot TestPack Plus™ hCG-COMBO.

|          | Unotech<br>AccuTest™ hCG-Urine | Abbott<br>TestPack Plus™ hCG-COMBO |
|----------|--------------------------------|------------------------------------|
| Positive | 70                             | 70                                 |
| Negative | 127                            | 127                                |

The following experiments were carried out to evaluate the sensitivity of AccuTest™ hCG-Urine at low end and high end levels of hCG. Urine samples with hCG concentrations of 0, 25, 50, 10<sup>2</sup>, 10<sup>3</sup>, 10<sup>4</sup>, 10<sup>5</sup>, 5x10<sup>5</sup> and 10<sup>6</sup> mIU/mL were tested. The results are presented below.

| hCG (mIU/mL) | 0  | 25 | 50 | 10 <sup>2</sup> | 10 <sup>3</sup> | 10 <sup>4</sup> | 10 <sup>5</sup> | 5x10 <sup>5</sup> | 10 <sup>6</sup> <i>1 million</i> |
|--------------|----|----|----|-----------------|-----------------|-----------------|-----------------|-------------------|----------------------------------|
| # of samples | 10 | 10 | 10 | 10              | 10              | 10              | 10              | 10                | 10                               |
| Positive     | 0  | 10 | 10 | 10              | 10              | 10              | 10              | 10                | 10                               |
| Negative     | 10 | 0  | 0  | 0               | 0               | 0               | 0               | 0                 | 0                                |

The results demonstrate that the Unotech AccuTest™ hCG-Urine Test can detect hCG in urine at levels as low as 25 mIU/mL and as high as 1,000,000 mIU/mL.

These results establish that the Unotech AccuTest™ hCG-Urine Test is substantially equivalent to the Abbott Test Pack Plus™ hCG-COMBO Test.

The intended use of the Unotech AccuTest™ hCG-Urine is for the early detection of pregnancy by the qualitative determination of human chorionic gonadotropin (hCG) in human urine. Our intent is to market this product to physicians' offices laboratories and clinical laboratories in the U.S.A. as well as in the foreign countries.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUN 11 1997

Ken Wu, Ph.D.  
• President  
Unotech Diagnostics Inc.  
2235 Polvorosa Avenue, Suite 220  
San Leandro, California 94577

Re: K971886  
Unotech AccuTest™ hCG-Urine  
Regulatory Class: II  
Product Code: JHI  
Dated: May 21, 1997  
Received: May 22, 1997

Dear Dr. Wu:

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 (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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

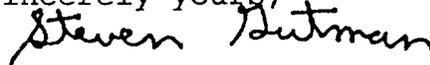
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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): K971886

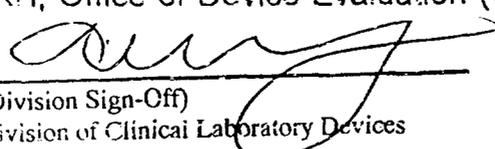
Device Name: AccuTest hCG-Urine

Indications For Use:

The intended use of the Unotech AccuTest hCG-Urine is for the qualitative determination of human chorionic gonadotropin (hCG) in human urine for the early detection of pregnancy. We intend to market this product to physicians' offices laboratories and clinical laboratories in the U.S.A. as well as in the foreign countries.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices

510(k) Number \_\_\_\_\_

Prescription Use   
Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)