OCT 20 1997

510K SUMMARY OF HEMAPROMPT for use in detection of gastric and fecal occult blood.

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

The HemaPrompt slide, used with a buffered developer, is a guaiac based test for the detection of occult blood in both gastric and fecal samples. The test is not affected by low pH. When used with gastric specimens, it is free from interferences by normal therapeutic concentrations of iron, ranitidine, cimetidine and antacids.
When a gastric or fecal specimen containing blood is applied to the HemaPrompt test paper, hemoglobin from the lysed blood cells in the sample comes in contact with the guaiac in the paper. The developer, a buffered solution of alcohol and hydrogen peroxide, is applied by pulling the tab on the slide and creates a guaiac / peroxidase-like reaction in the presence of hemoglobin which in turn causes a blue coloration in the test paper. This test will turn blue in the presence of more than 2 mg Hb/ G stool and more than 200 mcg Hb/ ml gastric juice
As with any occult blood test, results with HemaPrompt cannot be considered conclusive evidence of the presence or absence of upper or lower bowel bleeding or pathology. HemaPrompt is designed for use as a preliminary screening aid and is not intended to replace other diagnostic procedures such as endoscopy or Xray procedures.

EXPECTED AND PERFORMANCE RESULTS

The use of guaiac impregnated paper for the detection of **fecal occult blood** has been extensively studied. These clinical studies indicate that guaiac impregnated slide tests yield a positive result 3-5% of the time in screening programs and the percent of false positive results lies in the range of 1-2% of persons on a controlled diet i.e. a diet excluding substances such as raw/ rare meat, and raw peroxidase-containing vegetables such as broccoli and cauliflower, with the normal daily fecal blood loss in an adult lying in the range of 1-2 mls. of blood per 100 gram of stool. Sensitivity (% of subjects with the condition being sought who test positive) is difficult to estimate, but in series of patients with known colorectal cancer, 50-87% have been reported to yield positive reactions. Estimates of positive reactions with adenomatous bleeding have varied widely, and appear dependant to a degree on the size of polyp, with polyps less than 2 cms yielding less than 5% positive reactions.
Feces Study: Stool from a healthy volunteer on a diet as described was used as a baseline specimen and assumed to contain 1 ml of blood / 100 G of stool which is about the normal daily blood loss of an adult. Blood (Hb 14G/dl by Coulter) was diluted in the stool by homogenization to provide concentrations of 0.1, 0.2, 0.4 and 0. 6 grams hemoglobin per 100 grams of stool. In an anemic person with a hemoglobin of 10G/dl these levels would be achieved with approximately 1, 2, 4 and 6 mls. of blood per 100 grams of stool. These dilutions were used to test the sensitivity of HemaPrompt as well as to compare the reactions to those obtained with another commercially available guaiac slide test concurrently with HemaPrompt on the same specimens four times on three occasions over a period of twelve days, with precautions taken to avoid specimen desiccation.
HemaPrompt reacted positively at total hemoglobin concentrations of 2mg/G of stool (i.e. about twice the expected normal blood loss) or greater, in 60 seconds, with no reactions below this concentration. Hydrating stool (unless dried by age) by adding distilled water may produce reactions below this level (2mg/G) by eluting blood out of the sample onto the test paper resulting in a possible false positive reaction.

It was concluded that with **stool**, HemaPrompt reacted reliably and definitely to all hemoglobin levels above 2mg/G of stool. It was also concluded that HemaPrompt with a buffered developer reacted in the same way as another commercially available guaiac test with buffering.

The significance of **gastric occult blood** has been less extensively studied than fecal occult blood. One study of 153 gastric aspirates from 50 intubated healthy adults indicated all aspirates with more than 50 micrograms of hemoglobin/ ml were positive with a buffered guaiac impregnated test paper. There was an apparent overall false positive rate of 25.5% in this study of normal intubated individuals, but even using less than 25 micrograms of hemoglobin / ml. as the test cut-off, 11.8% showed a positive reaction. The positive rate will be affected by the method of collection. A traumatic

intubation can be expected to produce some degree of bleeding .

Gastric Juice Study: HemaPrompt was studied with

a) 12 patient gastric samples obtained by gastroscopy.
b) 8 healthy volunteer gastric samples obtained by intubation.
c) samples of a synthetic gastric juice of Phosphate Buffered Saline (PBS) each titrated with HCl to give pH's ranging from 1.0 to 7.0 and hemoglobin concentrations of 50, 100, 200 and 500 mcg/ml.

(a) It was found of the patient samples, none were positive initially, 37.5% (3/8) were positive with blood added to produce a concentration of 50 mcg / ml Hb, and 66% (8/12) were positive with 100 mcg / ml Hb and 100% of samples with blood added in concentrations of 200 mcg Hb / ml or greater reacted positively.

(b) Of the volunteer samples, 37.5% (3/8) were positive with no added blood. 60% (3/5) were positive with 20 mcg/ml Hb added, 87.5% (7/8) were positive with 50 mcg/ml Hb added to the specimen, and 100% were positive at concentrations of 100 mcg / ml and greater of added hemoglobin. All samples with blood added in concentrations of 200 mcg Hb / ml or greater reacted positively, and all reacted in less than 60 seconds. The positive rate will be affected by the method of collection. A traumatic intubation can be expected to produce some degree of bleeding. An initial negative result under these circumstances assumes added weight compared to a positive result..

(c) Of the PBS samples, 50 mcg Hb/ ml produced a positive reaction 44% (7/16) of the time, with 100 mcg / ml 81.25% (13/16) of samples showed a positive reaction. At 200 mcg / ml and above all samples showed a positive reaction. Furthermore, concentrations of ranitidine, cimetidine, ferrous sulfate, and an antacid (Mylanta) to be expected in the stomach after a maximum recommended dosing did not alter the HemaPrompt results. This does not necessarily apply in overdose situations when excessive iron compounds and certain H2 blockers (e.g. cimetidine/Tagamet) could produce false positive reactions, and excess antacid or Zantac (ranitidine) could produce a false negative.

The samples from each person were repeated over a two week period. Results demonstrated excellent HemaPrompt reproducibility at levels above 200 mcg/ ml gastric juice with all samples stored up to 10 days at 5^{0}C and showed excellent comparison to results obtained on the same samples with another commercially available test for this purpose

It was concluded that with **gastric juice**, HemaPrompt reacted reliably and definitely to hemoglobin levels above 200mcg / ml. gastric juice.

All monitors reacted in the expected manner (+ve turned blue). Exposing the guaiac paper to UV light for ten minutes inactivated the expected reaction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 20 1997

Robert Schreiber, M.D.
CEO
Aerscher Diagnostics, Inc.
358 High Street
Chestertown, Maryland 21620

Re: K972763
Trade Name: HemaPrompt for Fecal and Gastric Occult Blood
Regulatory Class: II
Product Code: KHE
Dated: July 22, 1997
Received: July 24, 1997

Dear Dr. Schreiber:

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 current Good Manufacturing Practice requirement, 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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): K972763

Device Name: HemaPrompt

Indications For Use:

HemaPrompt is a guaiac-based in-vitro slide method for the qualitative detection of occult blood in feces and gastric aspirate or vomitus by medical professionals only.

For fecal testing, it is a useful aid in the diagnosis of a number of gastro-intestinal disorders, and is recommended for use in 1) routine physical examinations 2) routine hospital testing 3) screening for colorectal cancer or gastro-intestinal bleeding from any other source.

For the testing of gastric contents it is used for the early detection of occult blood in conditions such as gastric trauma, gastric or duodenal ulceration, gastric cancer, esophageal varices, situations of likely exogenous or endogenous gastritis, leukemia, and hereditary telangiectasia. These conditions may be encountered in the emergency room, recovery room or intensive care.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maples

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

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

(Optional Format 1-2-96)