

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

K031356

B. Analyte:

Hemaprompt Gastric

C. Type of Test:

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

D. Applicant:

Aerscher Diagnostic

E. Proprietary and Established Names:

F. Regulatory Information:

1. Regulation section:

21 CFR Part 864.6550 Reagent Occult Blood

2. Classification:

Class II

3. Product Code:

KHE

4. Panel:

Hematology (81)

G. Intended Use:

1. Indication(s) for use:

HemaPrompt Gastric is a guaiac-based in-vitro slide method for the qualitative detection of occult blood gastric aspirate or vomitus by medical professionals only. For the testing of gastric contents it is used for the

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.

2. Special condition for use statement(s):

N/A

3. Special instrument Requirements:

N/A

H. Device Description:

HemaPrompt Gastric is a version of the laboratory guaiac slide test for gastric occult blood, and is composed of buffered guaiac-impregnated paper mounted on a cardboard frame which permits sample applications to one side with development and interpretation from the reverse side. Gastric contents containing occult blood contacts the guaiac impregnated paper and a pseudoperoxidase reaction occurs when developing solution is brought into contact with the guaiac paper. The test paper will turn blue in the presence of more than 100 mcg hemoglobin/ml of gastric fluid in less than 60 seconds. Monitors on the guaiac slide indicate if the chemicals are functioning correctly.

I. Substantial Equivalence Information:

1. Predicate device name(s):

HemaPrompt fg

2. Predicate K number(s):

K9972763

3. Comparison with predicate:

| Similarities | | |
|---------------------------------------|-------------------|--------------------|
| Item | Device | Predicate |
| Guaiac-peroxidase reaction slide test | Same | Same |
| Differences | | |
| Item | Device | Predicate |
| Developing Solution | External dropper | Pregnated on slide |
| pH Indicator | External-included | Not included |
| Sample type | Gastric | Stool |

J. Standard/Guidance Document Referenced (if applicable):**K. Test Principle:**

The use of guaiac as a test for the presence of blood is based on the oxidation of phenolic compounds present in guaiac to quinines, resulting in the production of a blue color. If blood is present, the heme portion of the hemoglobin (Hgb) molecule can function in a pseudoenzymatic manner, catalyzing the release of oxygen from hydrogen peroxide which in turn causes the oxidation of guaiac.

L. Performance Characteristics (if/when applicable):1. Analytical performance:*a. Precision/Reproducibility:*

A total of 35 gastric samples were tested 4 times the same day, and 3 subsequent days on the same samples with 100 % precision for levels above 100 mcg/ml of hemoglobin. A 50% precision was seen in levels less than 50 mcg/ml of hemoglobin.

b. Linearity/assay reportable range:

N/A

c. Traceability (controls, calibrators, or method):

N/A

d. Detection limit:

50 mcg/ml of hemoglobin or greater

e. Analytical specificity:

Twenty batches of gastric juice obtained by aspiration from different individuals, ten with gastric pathology and ten from healthy volunteers. Each sample was divided into 5 further samples and the pH in each adjusted to produce samples at pH 1.0, 2.5, 4.0, 6.0, and 7.0 respectively (simulating the varying pHs likely to be encountered in gastric juices). Each of these samples had blood added to provide hemoglobin levels of 5.0, 10, 50, 100, 200, 500, mcg hemoglobin/ml gastric juice. In addition these samples were tested for cross reactivity with Ranitidine HCl (Zantac) 25 mg/ml per 150ml gastric juice, Ferrous Sulfate Liquid USP 60 mg/ml per 150 ml gastric juice, and Mylanta 10-20 ml per 150 ml gastric juice.

Conclusion: The reaction levels are not affected by pH (range 1-7), nor by ferrous sulfate, Zantac or Mylanta when taken at recommended doses.

f. Assay cut-off:

N/A

2. Comparison studies:

a. Method comparison with predicate device:

Twenty batches of gastric juice obtained by aspiration from different individuals, ten with gastric pathology and ten from healthy volunteers. Each sample was divided into 5 further samples and the pH in each adjusted to produce samples at pH 1.0, 2.5, 4.0, 6.0, and 7.0 respectively (simulating the varying pHs likely to be encountered in gastric juices). Each of these samples had blood added to provide hemoglobin levels of 5.0, 10, 50, 100, 200, 500, mcg hemoglobin/ml gastric juice. Compared to the HemaPrompt fg, levels of hemoglobin above 100 mcg/ml showed 100% agreement reaction within 60 seconds and 50% agreement for 50 mcg/ml and below.

b. Matrix comparison:

Gastric juice

3. Clinical studies:

a. Clinical sensitivity:

b. Clinical specificity:

c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:

5. Expected values/Reference range:

Negative, however there is a false positive rate of 25.5% in normal patients

M. Conclusion:

Based on the studies included in this study, I recommend the HemaPrompt Gastric is SE to the predicate.