**Hemoglobin/haptoglobin DUO**

*Immunochromatographic rapid test card for qualitative detection of hemoglobin and hemoglobin/haptoglobin complex in feces*

**Catalog #: AN1019D**

**INTRODUCTION**

Colorectal cancer is a leading cause of illness and death in the world. Fecal occult blood ("FOB") is a good indicator for monitoring bleeding from the gastrointestinal (GI) system. Since it may take several years for some colon polyps to transform into colorectal cancers, the detection of bleeding colon polyps is an effective way to screen for colorectal cancer at an early stage. The implementation of a procedure to screen for occult blood in fecal samples for adults of 50 years or older has reduced the incidences of colorectal cancer by 20% and mortality by 30%. But the free hemoglobin is not stable in gastrointestinal (GI) system, especially for upper Gl bleeding. The haptoglobin is an alpha 2-glycoprotein synthesized in the liver that binds hemoglobin irreversibly. The haptoglobin-hemoglobin complex is much more stable than free hemoglobin in feces samples and can improve the occult blood test sensitivity.

**SUMMARY AND PRINCIPLE OF THE TEST**

The test uses new homogenous immunochromatographic system with gold particles. It is a ready to use test which only needs a faecal sample dilution with the supplied ready to use diluent buffer. Specificity is ensured by using a monoclonal antibody conjugated with gold particles and directed against specific human hemoglobin or haptoglobin complex. The immunochromatographic test is coated with a monoclonal immunoreagent specific for human hemoglobin and haptoglobin.

**REAGENTS AND MATERIALS**

<table>
<thead>
<tr>
<th>FOB/HB-HP Extraction Vial Instruction for use</th>
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<tr>
<td>25pcs</td>
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<td>1.5mlx25</td>
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**PRECAUTION FOR USERS**

1. For in-vitro diagnostic use only.
2. Handle all specimens as if they contain infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving for at least one hour. Alternatively, treat with a 0.5 or 1% solution of sodium hypochlorite for one hour before disposal.
3. Wear protective clothing (laboratory coats and disposable gloves) when assaying samples.
4. Do not eat, drink or smoke in areas where specimens and kit reagents are handled.
5. Avoid contact between hands and eyes or nose during specimen collection and testing.

**SPECIMEN COLLECTION**

Stool samples must be taken as soon as the symptoms appear. Viral particles decrease in number after one week, making the diagnosis more difficult. The samples can be stored in the refrigerator for 1 to 2 days. For longer storage they must be kept frozen at -20°C. In this case, the sample should be totally thawed, and brought to room temperature and homogenised before testing.

**STORAGE OF TEST KIT**

The hemoglobin/haptoglobin test can be stored at any temperature between 4-30°C. Do not freeze. The stability of the kit under these storage conditions is 24 months. Use up the reagents as soon as possible after the kit is unpacked.

**ASSAY PROCEDURES**

**Preparations:**

Allow all reagents and samples to equilibrate to room temperature before proceeding with the test.

**Procedure:**

1. Unscrew the cap of the Sample Extraction Vial. Collect sample by immersing the applicator stick into the faeces ensuring that the sample has impregnated the stick surface properly. (about 50mg). For liquid or semi-solid stools add 100 microliters of stool using an appropriate pipette into the vial.
2. Reinsert the applicator stick into the vial and screw the cap tightly. Shake the vial to release the virus into diluent.
3. Break the tip off. Add 3 drops to the sample well of the test device.
4. Incubate the test at room temperature and read the test after 5-15 minutes.

**INTERPRETATION OF RESULTS**

**Negative:** One pink line appears in control line, showing the test has been carried out correctly. There will be no line in test region.

**Positive:** In addition to a pink colored control line, for hemoglobin positive, a HB test line near to sample well will appear. For haptoglobin positive, a HB/HP test line will appear.

**Invalid:** A total absence of color in both regions is an indication of procedure error and/or that the test reagent has deteriorated. The test should be repeated using a new test.

**LIMITATIONS OF THE ASSAY**

1. The test must be carried out within 1 hour of opening the sealed bag.
2. An excess of stool sample could result in wrong results.
3. Patients suffering from menstrual period, bleeding hemorrhoids, blood in urine or strain during bowel movement should not collect samples.
4. Positive results confirm the presence of human hemoglobin or human transferrin in fecal samples; nevertheless, it can be also due to several causes besides colorectal bleeding, such as hemorrhoids, blood in urine or stomach irritations. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source of the blood in the stool.
5. Negative results do not exclude bleeding, as some polyps and colorectal cancers may bleed intermittently or not during certain

**PERFORMANCE**

**Sensitivity**

The Biocare hemoglobin/haptoglobin test can detect hemoglobin at 25ng/ml and haptoglobin-hemoglobin complex at 25ng/ml diluted in extraction buffer provided.

**Specificity**

The Biocare hemoglobin/haptoglobin test is specific for human hemoglobin and human haptoglobin complex, showing no cross-reaction with hemoglobin or transferring, haptoglobin from bovine, sheep, goat, horse and pig.

**Manufacturer:**

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