To use unscrew the white cap on the sample bottle. Add four drops of the Interference Testing control. Replace the white cap and shake vigorously. Follow step three of the patient test procedure. If controls do not perform as expected, do not use the test results. Repeat the test or call Wampole Technical Service at 800-257-9525.

Cross reactivity studies were completed to investigate the cross reactivity of other species of hemoglobin (Hb) and tissue extracts on the Clearview ULTRA FOB Test and another commercially available FOB tests. Hb of bovine, equine, pig, rabbit, sheep, fish, chicken and goat origin was added to the test device to determine the cross reactivity of the test with Hb of other species. Each Hb species was added to normal stool extracts at both 0 and 50 ng/ml human hemoglobin (HbH). The results were as expected. The negative results continued to be negative and the positive results continued to be positive after the addition of the animal hemoglobins. The study was repeated with tissue extracts of beef, pig, rabbit, sheep, fish and chicken and no cross reactivity was evident.

**EXPECTED VALUES**

Positive rates with immunochromal occult blood tests have been shown to vary in each patient population depending on the test used, age and ethnicity of the patient and the predisposition to colorectal disease and other factors that may be associated with lower gastrointestinal bleeding. The Clearview ULTRA FOB Test will detect Hb in feces at levels as low as 50 ng/ml.

**PERFORMANCE CHARACTERISTICS**

**Sensitivity**

Reproducibility studies were conducted at three Physician Office Labs (POL). 100 human hemoglobin-free stool extracts were collected and separated in five groups of twenty. Each group of specimens were spiked with a known level of human hemoglobin to result in the following concentrations: 0 ng/ml, 30 ng/ml, 50 ng/ml, 70 ng/ml and 200 ng/ml (prozone). The total number of determinations per level of hemoglobin was 60. The results were compared with results from a reference laboratory. There was 99.3% agreement between the results obtained from the POL and the results obtained from the reference laboratory. The overall accuracy of the Clearview ULTRA FOB Test by the POL users was 98.9%.

**Specificity**

The specificity of the Clearview ULTRA FOB Test was evaluated from cross reactive studies with known amounts of hemoglobin (Hb), Hb-S, Hb-C, at concentrations of 50 ng/ml. All of the Clearview ULTRA FOB Test results were positive.

**Interference Testing**

Cross reactivity studies were completed to investigate the cross reactivity of other species of hemoglobin (Hb) and tissue extracts on the Clearview ULTRA FOB Test and another commercially available FOB tests. Hb of bovine, equine, pig, rabbit, sheep, fish, chicken and goat origin was added to the test device to determine the cross reactivity of the test with Hb of other species. Each Hb species was added to normal stool extracts at both 0 and 50 ng/ml human hemoglobin (HbH). The results were as expected. The negative results continued to be negative and the positive results continued to be positive after the addition of the animal hemoglobins. The study was repeated with tissue extracts of beef, pig, rabbit, sheep, fish and chicken and no cross reactivity was evident.

**Dietary Testing**

A potential interference of dietary substances on the Clearview ULTRA FOB Test was assessed. Aqueous extracts of raw broccoli, cauliflower, cantaloupe, horseradish, red radish, parsnip and turmeric were added to the test device to determine if vegetable extracts cross react with the test. The extracts were prepared by homogenizing raw vegetable in a food processor and then subsequently centrifuging the extract to separate the solids and liquid phases. Dietary iron and vitamin C supplements and horseradish peroxide were also tested for cross reactivity. No cross reactivity was evident.

**REFERENCES**


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MATERIALS REQUIRED BUT NOT PROVIDED
• Timing Device
• External Controls (8102KCV Recommended)

STORAGE AND STABILITY
Store the Clearview ULTRA FOB Test at 2˚-30˚C (36˚-86˚F). DO NOT FREEZE. Test Strips are stable when stored at these temperatures until the expiration date printed on the labeling.

PRECAUTIONS
• For in vitro diagnostic use only.
• For professional and laboratory use.
• Do not reuse the test.
• Do not use test strips if canister is damaged; does not seal.
• Do not use sample probe tips or tips if canister is damaged; does not seal.
• The directions for use must be followed carefully for accurate results.
• Do not use test strips if canister is damaged; does not seal.

SPECIMEN COLLECTION AND HANDLING
Collect feces from the collection paper or from specimen caught in a clean cup. Contamination from toilet water should be avoided.

1. Fill in all required information on the sampling bottle.
2. Open green cap by turning to the left pulling upwards.
3. Scrape the surface of the fecal sample with the sample probe.
4. Cover the grooved portion of the sample probe completely with stool sample.
5. Close sampling bottle by inserting the sample probe and screwing cap on tightly to the right. Do not reopen.
6. Extracted feces may be stored at room temperature for up to 5 days or can be refrigerated at 2-8˚C for up to 14 days.
7. Bring extractions to room temperature prior to assaying and mix well before sampling.

TEST PROCEDURE
Refer to Figure 1.
2. Remove a Clearview ULTRA FOB Test strip from the canister. Minimize the amount of time that the canister is left open and assure that the canister is securely closed after opening.
3. Remove the white cap on the extraction vial. Drop the sample end of the dipstick into the extraction vial.
4. Start timer.
5. When the timer reaches 5 minutes, read results. Read results as shown under “Interpretation of Results”.

NOTE: Specimens with high concentrations of Hb may produce positive results in as little as 1 minute. Confirm negatives at 5 minutes. Do not read after 10 minutes.

FIGURE 1

INTERPRETATION OF RESULTS

POSITIVE
Carefully look for the appearance of a test line in the Test Region. ANY blue colored line, NO MATTER HOW FAINT, in the Test Region with a colored line in the Control Region is a positive result. Neither the intensity nor the color should be compared to that of the Procedural Control line.

NEGATIVE
If no blue line appears in the Test Region and one line in the Procedural Control Region the result is negative.

INVALID
If no line appears in the Procedural Control Region, the test is invalid and must be repeated with a new dipstick.

QUALITY CONTROL
Good laboratory practices recommend the use of appropriate controls. There are two types of controls for the Clearview ULTRA FOB test, the internal procedural control and external controls.

Procedural Control
The Procedural Control is found in the Procedural Control Region of the test strip. This control assures the operator that (A) the sample addition and migration through the test strip has occurred and that (B) the control anti-mouse antibody and the reporter MAb are intact and functional. This control does not ensure that the capture antibody is accurately detecting the presence or absence of Hb in the sample.

External Control
External controls are used to assure the operator that the capture and conjugated antibodies are present and reactive. External controls will not detect an error in performing the patient test procedure. Controls should be assayed once per kit.