QUICKVUE®
iFOB TEST
Immunochemical Fecal Occult Blood

CLIA Complexity: WAIVED

INTENDED USE

The QuickVue iFOB (immunochemical Fecal Occult Blood) test is an immunochemical device intended for the qualitative detection of fecal occult blood by laboratories or physicians' offices. It is useful in determining gastrointestinal (GI) bleeding found in a number of gastrointestinal disorders, such as: diverticulitis, colitis, polyps, and colorectal cancer. This test is recommended for use in: (1) routine physical examinations or when hospital patients are first admitted, (2) hospital monitoring for GI bleeding in patients, and (3) screening for colorectal cancer or gastrointestinal bleeding from any source.

SUMMARY AND EXPLANATION

The American Cancer Society and Centers for Disease Control recommend a fecal occult blood test annually after age 50 to aid in the early detection of colorectal cancer.[1]

- The Guaiac test is widely available but lacks high accuracy. Guaiac is a naturally occurring phenolic compound that can be oxidized to quinone by hydrogen peroxidases with a detectable color change. The sensitivity and specificity of Guaiac tests are much lower than those of Immunochemical assays. The low accuracy of the Guaiac dye method is related to dietary peroxidases, including hemoglobin and myoglobin from meat and uncooked fruits and vegetables. Additionally, iron intake may cause false positive results with Guaiac tests.[2]
- **The QuickVue iFOB test is much more sensitive and has been designed to be more specific in detecting low levels of human fecal occult blood.** It is highly accurate compared to the Guaiac method. The results of immunochemical FOB rapid tests are not affected by dietary peroxidases, animal blood or ascorbic acid. A Japanese study demonstrated using immunochemical FOB tests reduced colorectal cancer-related mortality by 60%.[3]

PRINCIPLE OF THE TEST

The QuickVue iFOB test is a one-step lateral flow chromatographic immunoassay. The test strip consists of: (1) a burgundy colored conjugate pad containing mouse anti-hHb antibodies conjugated with colloidal gold and (2) a nitrocellulose membrane strip containing a Test line (T-line) and a Control line (C-line). The T-line is coated with anti-hHb antibodies, and the C-line is coated with goat anti-mouse IgG antibodies.

When the correct volume of test specimen is dispensed into the sample well of the device, the test specimen migrates across the test strip. If the concentration of hHb in the specimen is at or above 50 ng hHb/mL or 50µg hHb/g feces, the T-line appears as a visible burgundy line. If the concentration of hHb in the specimen is below the detectable level, no T-line develops.

The C-line is coated with goat anti-mouse antibody, which binds to the conjugated monoclonal antibody, regardless of the presence of hHb in the specimen.

REAGENTS AND MATERIALS SUPPLIED

Description/Catalog #	20194	20205
Individually Wrapped Test Cassettes	20	100
Package Insert	1	1
Procedure Card	1	0
Specimen Collection and Return Kits, each consisting of: ■ Specimen Collection Tube (1), with 2 mL FOB buffer (1x PBS with 0.02% sodium azide) and Patient Identification Label ■ Specimen Collection Paper with Adhesive (1) ■ Specimen Pouch (1) ■ Absorbent Sleeve (1) ■ Return Mailer (1) ■ Patient Instructions (1)	20	0

MATERIALS REQUIRED BUT NOT PROVIDED

■ Timing Device.

WARNINGS AND PRECAUTIONS

- The QuickVue iFOB test is for *in vitro* diagnostic use.
- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Dispose of containers and used contents in accordance with Federal, State and Local requirements.
- Use of Nitrile or Latex gloves is recommended when handling potentially infectious fecal specimens.[4,5]
- Follow proper hand washing hygiene after handling potentially infectious fecal specimens.
- The Test Cassette must remain sealed in the foil pouch until just prior to use.
- Treat all specimens and used assay materials as if they are infectious.[4,5]
- To obtain accurate results, you must follow the Package Insert instructions.

KIT STORAGE AND STABILITY

Store the kit at room temperature 59–86°F (15–30°C), out of direct sunlight. Do not expose kit components to temperatures over 86°F (30°C). Kit contents are stable until the expiration date printed on the outer box. Do not freeze.

The following instructions for Specimen Collection and Storage apply to Catalog # 20194.

Specimen collection kits may be ordered separately using Catalog # 20196 (10 collection kits) and # 20204 (40 collection kits).

SPECIMEN COLLECTION AND STORAGE

The specimen used in this assay is feces. In most cases, the patient will collect the specimen at home. In the event that the specimen is collected at the physician's office or lab, the patient will follow the procedure outlined below.

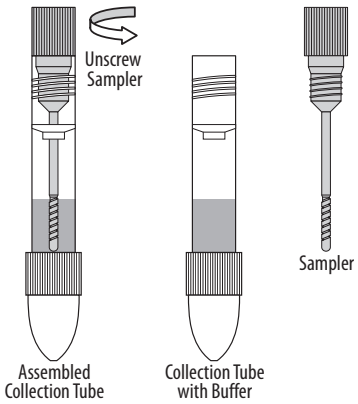
1. Enter the Patient Identification information on the Collection Tube label.

NOTE: *Do not allow fecal specimen to contact toilet water until after the sample has been collected. Do not urinate on fecal specimen or Collection Paper.*

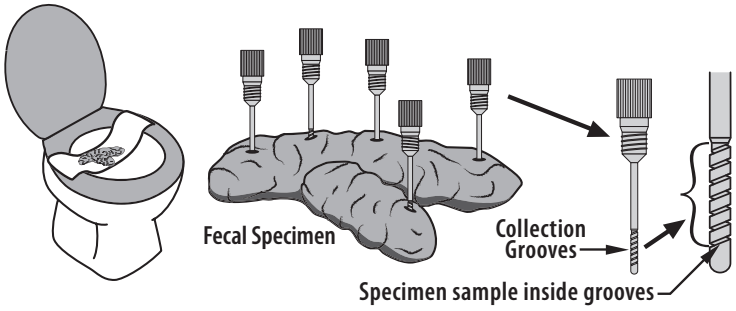
2. Attach Collection Paper to toilet seat.

- **a.** Raise toilet cover.
- **b.** Remove tape cover from each end of the Collection Paper.
- **c.** Position Collection Paper on rear half of seat, allowing paper to sag.
- **d.** Press the tape down on each side of the seat.
- **e.** Deposit fecal specimen on Collection Paper.
- **f.** Do not remove the Collection Paper from the toilet seat.

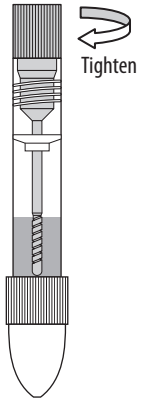
3. Unscrew the Sampler from the Collection Tube.



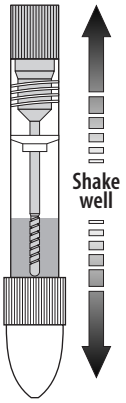
4. With the fecal specimen still on the Collection Paper, randomly pierce the specimen with the grooved end of the Sampler in **at least five (5) different sites.**



5. Insert the Sampler into the Collection Tube and firmly tighten it.



6. Shake the tube to mix the specimen and the FOB buffer.



7. Flush remaining specimen and used Collection Paper.

NOTE: *Specimens collected may be stored up to eight (8) days at ambient temperatures below 95°F (35°C), six (6) months at 36–46°F (2–8°C) or two (2) years at -4°F (-20°C).*

QUALITY CONTROL

Built-in Control Features

The QuickVue iFOB test contains a built-in control feature, the Control line (C-line). The presence of this burgundy C-line indicates that an adequate specimen volume was used and that the reagents migrated properly. If a C-line does not form, the test is considered invalid. In this case, review the entire procedure and repeat the test with a new device.

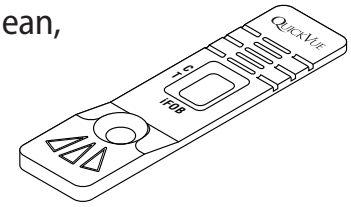
External Quality Control

Good laboratory practice recommends the use of external quality controls to assure the functionality of reagents and proper performance of the test procedure. For this purpose, we recommend using the QuickVue iFOB Control Set (Catalog Number: 20197). External Controls should be tested following the Test Procedure section. If the controls do not perform as expected, repeat the test or contact Quidel Technical Support before testing patient specimens.

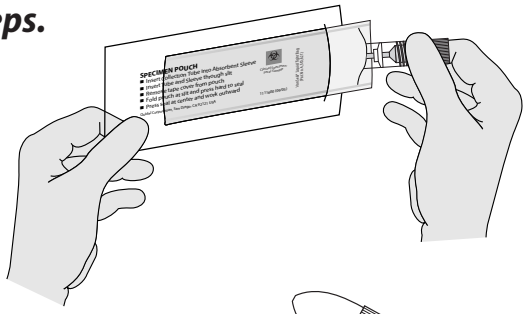
TEST PROCEDURE

All Test Cassettes and clinical specimens must be at room temperature before beginning the test.

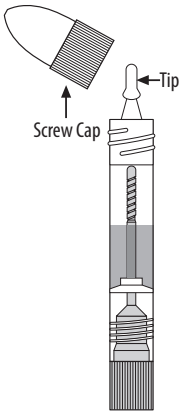
- Remove the Test Cassette from the pouch and place it on a clean, flat, dry, level surface.



Put on gloves before performing the following steps.

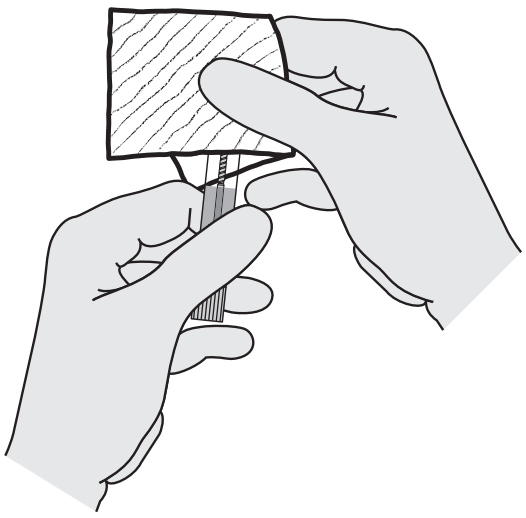


- Remove Absorbent Sleeve from Specimen Pouch.
- Remove Collection Tube from Absorbent Sleeve.

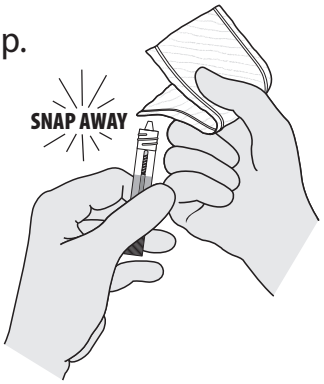


- Shake the Collection Tube to mix the specimen and the FOB buffer.
- Hold the Collection Tube upright, as shown.
- Remove the light blue screw cap by turning.

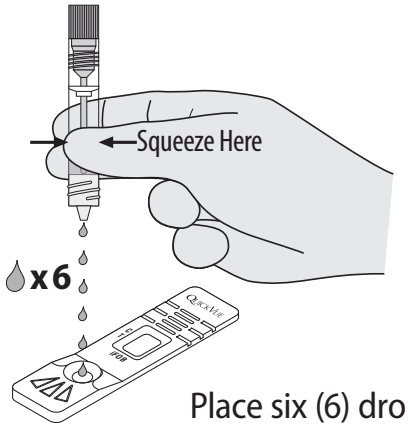
- **Fully cover tip with absorbent material to avoid potential contact with specimen solution.**



- **QUICKLY** snap off tip.
- DO NOT TWIST.



- Holding the Collection Tube **vertically,** dispense **six (6) drops** of specimen solution from the Collection Tube into the center of the Sample Well.



Place six (6) drops in center of well

- **READ RESULTS AT 5–10 MINUTES.**
  Some positive results may be seen earlier.
  IMPORTANT: Do not read the test results after ten (10) minutes.

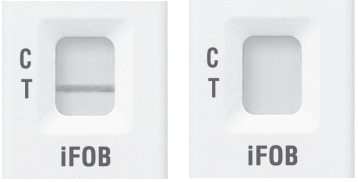
INTERPRETATION OF RESULTS

Refer to the Procedure Card or printed tray for visual color interpretation of the Test and Control Lines. Both the T-line and the C-line present as the same burgundy color.

Positive Result:
If both a C-line and a T-line are present, the result is positive. A positive result indicates the level of hHb in the specimen is at or above the detection level.

Negative Result:
If only the C-line develops in the control region of the test strip, the result is negative.

Invalid Result:
If no C-line appears within 5 minutes, the result is invalid and the assay should be repeated with a new device. ***NOTE:*** *The test line may or may not be present. However, the absence of a control line indicates an invalid test.*



LIMITATIONS

The QuickVue iFOB test is intended only for the detection of human hemoglobin in feces.

- Results cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source of the occult blood in the feces.
- A negative result can be obtained even when a gastrointestinal disorder is present. For example, some polyps and colorectal cancers may bleed intermittently or not at all during certain stages of the disease.
- False negative results may occur when occult blood is not uniformly distributed throughout the bowel movement and the formation of a fecal specimen. Repeat testing is recommended if a pathological condition is suspected.

Patients with the following conditions should not be considered for testing, as these conditions may interfere with test results:

- Menstrual bleeding
- Bleeding hemorrhoids
- Constipation bleeding
- Urinary bleeding

However, these patients may be considered for testing after such bleeding ceases.

Alcohol and certain medications such as aspirin, indomethacin, reserpine, phenylbutazone, corticosteroids and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding in some patients.

EXPECTED RESULTS

The QuickVue iFOB test will show positive results if there is a detectable amount of human hemoglobin in the specimen. The detection level is 50 ng hHb/mL buffer or 50 µg hHb/g feces.

PERFORMANCE CHARACTERISTICS

Sensitivity
The sensitivity of the test is 50 ng hHb/mL buffer or 50 µg hHb/g feces.

Accuracy
Reference Laboratory and Physicians' Office Laboratory (POL) Studies

One hundred (100) hHb-free feces extraction specimens collected in-house were divided into 5 groups of 20 each. The five groups of extraction specimens were spiked with hHb for five different concentrations, respectively: 0, 37.5 ng hHb/mL, 50 ng hHb/mL, 62.5 ng hHb/mL, and 2000 ng hHb/mL. Those specimens were blind labeled and tested with the QuickVue iFOB test at three (3) Physicians' Office Laboratories and a Reference Laboratory.

The results obtained from the three POL sites by persons with diverse educational background and work experience were 97.7% accurate, and the results from the Reference Laboratory were 99% accurate. Thus, overall the accuracy of the QuickVue iFOB test is 98%.

Specificity
The QuickVue iFOB test is specific to human hemoglobin. The following substances, when spiked in both positive and negative specimens, did not interfere with the test results.

Substance	Concentration (µg/mL)
Beef Hemoglobin	2,000
Chicken Hemoglobin	500
Fish Hemoglobin (meat extract)	100
Horse Hemoglobin	500
Goat Hemoglobin	500
Pig Hemoglobin	500
Rabbit Hemoglobin	60
Sheep Hemoglobin (meat extract)	100
Horseradish Peroxidase	20,000
Red radish	Aqueous extract
Raw turnip	Aqueous extract
Cauliflower	Aqueous extract
Broccoli	Aqueous extract
Parsnip	Aqueous extract
Cantaloupe	Aqueous extract
Vitamin C (ascorbic acid)	Dietary supplement
Iron	Dietary supplement

ASSISTANCE

If you have any questions regarding the use of this product, please call Quidel's Technical Support number, (800) 874-1517 (toll-free in the U.S.A.) or (858) 552-1100, Monday through Friday, between 7:00 a.m. and 5:00 p.m. Pacific Time, U.S.A. If outside the United States, contact your local distributor or technicalsupport@quidel.com.

REFERENCES

1. American Cancer Society, Inc. Cancer Reference Information: Can Colon and Rectum Cancer Be Found Early? [Online] Available: http://www.cancer.org

2. Allison JB, Takawa IS, Ransom LJ, Adrian AL. A comparison of fecal occult blood tests for colorectal-cancer screening. N Engl J Med 1996; 334:155–159.

3. Saito H. Screening for colorectal cancer by immunochemical fecal occult blood testing (Review). Jpn J Cancer Res 1996; 87:1011–1024.

4. Recommendations for the Prevention of HIV Transmission in Health Care Settings, Morbidity and Mortality Weekly Report, Centers for Disease Control, August, 1987.

5. Biosafety in Microbiological and Biomedical Laboratories, 4th Edition. U.S. Department of Health and Human Services, CDC, NIH, Washington, DC (1999).

REF 20194 – QuickVue iFOB test 20 test kit
20205 – QuickVue iFOB test 100 test kit
20196 – QuickVue iFOB test Specimen Collection and Return Kit (10 kits)
20204 – QuickVue iFOB test Specimen Collection and Return Kit (40 kits)

IVD

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Manufacturer

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