iFOB Control Set

(Negative and Positive)

INTENDED USE

The QuickVue iFOB Control Set is intended for use with the QuickVue iFOB (immunochemical Fecal Occult Blood) test. These controls provide an aid in the interpretation of positive and negative test results and verify proper test performance.

SUMMARY AND EXPLANATION

The QuickVue iFOB Control Set contains two vials – one negative and one positive – for use in verifying the performance of the QuickVue iFOB test. Elevated levels (50 ng hHb/mL buffer or 50 µg hHb/g feces) of human hemoglobin are an indication of gastrointestinal disorders such as diverticulitis, colitis, and polyps, which may lead to colorectal cancer if not treated.

When used as qualitative controls in place of patient specimen, the results may aid in the interpretation of positive and negative results and verify test performance.

PRINCIPLE OF THE TEST

The QuickVue iFOB Control Set is designed for use as external qualitative control samples when used in accordance with the QuickVue iFOB test package insert procedure.

REAGENTS AND MATERIALS SUPPLIED

- One (1) vial (2.0 mL) Negative Control: Contains buffered solution, with 0.02% sodium azide as preservative.
- One (1) vial (2.0 mL) Positive Control: Contains hemoglobin of human origin in buffered solution, with 0.02% sodium azide as preservative.
- Package Insert (1)

MATERIALS REQUIRED BUT NOT PROVIDED

- QuickVue iFOB test cassette
- Timer or watch

WARNINGS AND PRECAUTIONS

- For *In-Vitro* Diagnostic Use.
- Do not use beyond labeled expiration date marked on the outer kit label.
- Do not interchange the caps with those of other reagent bottles.
- Dispose of containers and used contents in accordance with Federal, State, and Local requirements.
- Use of Nitrile or Latex gloves is recommended when working with these controls.
- Follow proper hand washing hygiene after handling these controls.
- The External Controls are designed for use only with the QuickVue iFOB test.

These components may contain material of human origin, which has been tested using FDA-approved methods and has been found negative to human immunodeficiency virus (HIV-I and HIV-II), antibody to Hepatitis C virus and for Hepatitis B surface antigen (HbsAg). No known test method can offer total assurance that HIV-I and HIV-II, Hepatitis B virus, Hepatitis C virus or other infectious agents are absent. **HANDLE THESE REAGENTS AS IF THEY WERE POTENTALLY INFECTIOUS.**

STABILITY AND STORAGE

Store the QuickVue iFOB test Control Set at room temperature 59–86°F (15–30°C). Do not freeze. The contents can be used until the expiration date printed on the outer box, or four (4) weeks after the vials are opened, whichever occurs first.

QUALITY CONTROL

External controls may be used to demonstrate that all reagents and assays are performing properly. The QuickVue iFOB Control Set, when used in accordance with the test procedure described in the QuickVue iFOB test package insert, provide this capability.

TEST PROCEDURE

All Test Cassettes and control reagent vials 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.
- Remove the control reagent vial screw cap by turning.
- Dispense **six (6) drops** of either the Positive or Negative control reagent into the Sample 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 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 (50 ng hHb/mL buffer or 50 µg hHb/g feces).

Negative Result:
If only the C-line develops in the control region of the test strip, the result is negative. A negative result indicates the hHb in the specimen is below 50 ng/mL.

Invalid Result:
If no C-line appears within 5 minutes, the test result is invalid and the control sample must be retested. An invalid result indicates either the assay was not performed correctly or the reagents were not working properly. If an invalid result occurs, retest the control sample using a new test unit. If the problem persists, please contact Quidel Technical Support.

LIMITATIONS

The QuickVue iFOB Control Set contains qualitative reagents, which are not to be used as quantitative calibrators. The controls should not be diluted and may be incompatible for use with other assays.

The QuickVue iFOB Control Set must be used at room temperature 59–86°F (15–30°C). Performance of the assay at other temperatures may yield invalid results.

EXPECTED VALUES

The QuickVue iFOB Control Set will produce examples of the color response to be expected for negative and positive specimens when tested with the QuickVue iFOB test.

The failure to obtain a negative result with the Negative Control or a positive result with the Positive Control indicates that the test was not performed properly or that the test reagents were not functioning properly.

If an inappropriate result is obtained for either the Negative or Positive Control, either repeat the test or contact Quidel Technical Support.

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.

REF 20197 - QuickVue iFOB External Control Set

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IVD
For *In Vitro* Diagnostic Use

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Temperature Limit