Abbott

REF 02FK10CE, 02FK16CE, 02FK17CE

Bioline™

HCV

Anti-HCV Test
Test de détection des anticorps anti-VHC
Prueba de VHC
Teste anti-VHC
TEST auf Anti-HCV

Materials provided and active ingredients of main components

1. The Bioline™ HCV test kit contains the following items to perform the assay:

Catalog No.	Contents
02FK10CE	1. 30 Test devices with desiccant in individual foil pouches 2. Assay diluent (1 x 5 ml/vial) 3. 1 Instructions for use
02FK16CE	1. 25 Test devices with desiccant in individual foil pouches 2. Assay diluent (1 x 5 ml/vial) 3. 25 Capillary pipettes (10 µl), 25 Sterile lancets, 25 Alcohol swabs 4. 1 Instructions for use
02FK17CE	1. 25 Test devices with desiccant in individual foil pouches 2. Assay diluent (1 x 5 ml/vial) 3. 25 Capillary pipettes (10 µl), 25 Safety lancets, 25 Alcohol swabs 4. 1 Instructions for use

2. Active ingredients of main components

- 1 Test device includes:
  - Gold conjugates: Protein A – gold colloid (1.0±0.2 µg)
  - Test line: Recombinant HCV antigen (core, NS3, NS4, NS5) (1.5±0.3 µg)
  - Control line: Goat anti-human Immunoglobulin (2.0±0.4 µg)
- Assay diluent includes: 50 mM Tris-HCl Buffer (5 ml), Sodium azide (0.02 %)

Materials required but not provided

- Micropipette, Protective gloves, Timer, Biohazard container

Kit storage and stability

1. The test kit should be stored at a temperature between 1 °C and 30 °C. Do not freeze the kit or its components.
2. Assay diluent may be opened and resealed for each assay. Cap should be firmly sealed between each use. Assay diluent is stable until expiration date if kept at 1 - 30 °C.
3. The test device is sensitive to both heat and humidity. Perform the test immediately after removing the test device from foil pouch.
4. Do not use the test kit beyond its expiration date. The shelf life of the kit is as indicated on the outer package.
5. Do not use the test kit if the pouch is damaged or the seal is broken.

Warnings

1. The test devices are for *in vitro* diagnostic use only. Do not reuse the test device.
2. The instructions must be followed exactly to achieve accurate results. Any individual performing an assay with this product must be trained in its use and must be proficient.
3. Do not use the pipette by mouth, smoke, drink, eat, apply cosmetics, or handle contact lenses in areas where specimens or kit components are being handled.
4. Wear protective gloves while handling specimens and wash hands thoroughly afterwards.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials in a biohazard container as if they were infectious waste.
7. Do not mix or interchange different specimens.
8. Do not eat the desiccant from the foil pouch.
9. Avoid splashing or aerosol formation of specimen and assay diluent.
10. Do not mix or interchange components among different lots or those for other products.
11. Do not drink assay diluent.
12. Care should be taken to avoid contamination of the bottle nozzle when dropping assay diluent into the specimen well.
13. The assay diluent contains a proprietary anti-microbial agent, sodium azide, which presents no hazard to the user if normal laboratory safety precautions are followed. If contact with assay diluent to the eyes and/or skin, wash affected area with soap and water immediately. If irritation or signs of toxicity occur, seek medical attention.
14. The assay diluent contains sodium azide, which may react with lead or copper plumbing to form highly explosive metal azide compounds. When disposing of these reagents through plumbing fixtures, flush with a large volume of water to prevent azide build-up in drains.
15. Even though the color of assay diluent is changed to faint yellow, it doesn't affect the performance and stability of the kit.

Specimen collection and storage

1. **Whole blood**

[Collection by venipuncture]

- Using venipuncture, draw the whole blood into the collection tube (containing anticoagulants including heparin, EDTA and sodium citrate).
- If the blood specimen is not immediately tested, it must be refrigerated at 2 - 8 °C.
- If stored at 2 - 8 °C, the blood specimen must be tested within 3 days of refrigeration.
- Do not use a blood specimen stored for more than 3 days; it can cause a nonspecific reaction.
- Bring blood specimens to room temperature (15 - 30 °C) prior to use.

[Collection using a lancet]

- Clean the area to be lanced with an alcohol swab.
- Squeeze the fingertip then prick the lateral side of the finger with a lancet provided. Wipe away the first blood drop. Then, safely dispose of the lancet immediately after.
- Immerse the open end of a new capillary pipette (10 µl) in the next blood drop and release the pressure to draw blood into the capillary pipette up to the fill line.

2. **Plasma or serum**

- [Plasma] Using venipuncture, draw the whole blood into the collection tube (containing anticoagulants including heparin, EDTA and sodium citrate) and then centrifuge blood to obtain the plasma specimen.
- [Serum] Using venipuncture, draw the whole blood into the collection tube (NOT containing anticoagulants) then leave for 30 minutes to allow blood coagulation to occur. Centrifuge the tube to generate a serum specimen.
- If plasma or serum specimens are not tested immediately, they must be refrigerated at 2 - 8 °C. For storage period longer than 2 weeks, freezing (below -20 °C) is required. Bring plasma or serum specimens to room temperature (15 - 30 °C) prior to use.
- Plasma or serum specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified by centrifugation prior to assaying.

3. **Precautions**

- Repeated frozen-thawed cycle for specimen should be avoided.
- Anticoagulants including heparin, EDTA and sodiu citrate do not affect the test result. Use of oth anticoagulants has not been validated. Their use ma affect the test result.
- Use new pipette tips for each specimen in order t avoid cross-contamination of other specimens whic could cause erroneous results.

Test procedure

1. Bring all kit components and specimens to reach temperature between 15 °C and 30 °C prior to testing.
2. Remove the test device from foil pouch and place it on a fla dry surface. Label the test device with a patient identifier.
3. **[Using a micropipette]**
   Dispense 10 µl of plasma, serum or whole bloo specimen into the specimen well marked "S".
   Or,
   [Using a capillary pipette]
   Dispense 10 µl of drawn whole blood specimen into th specimen well marked "S"
4. Dispense 4 drops of assay diluent into the specime well "S".
   ⚠ **Caution:** If you do not hold the bottle vertically, can lead to inaccurate results. Exactly, 4 drops shoul be added. Adding more than 4 drops may result i reddish color background or an invalid result.
5. As the test begins to work, you will see purple colo move across the result window in the center of the tes device.

Interpret test results 5 - 20 minutes after adding assay diluent. Do not read after 20 minutes.

⚠ **Caution:** If the test result is not legible after 5 minutes due to high background color, read again later but within 20 minutes of adding the diluent. Reading outside of this time frame (before 5 min or after 20 min) may result in false results.

Test interpretation

A colored control line will appear at "C" in the result window to show that the test is working properly. The "T" section of the result window indicates the test result.

Non-reactive result: The presence of only the control line (C) within the result window indicates a non-reactive result.

Reactive result: The presence of the test line (T) and the control line (C) within the result window, regardless of which line appears first, indicates a reactive result.

⚠ **Caution:** The presence of any test line, no matter how faint, the result is considered reactive.

- **Invalid result:** If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Instructions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be retested using a new test device.

Test limitations

1. A non-reactive result does not preclude the possibility of infection with HCV. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. Due to the inherent design of qualitative IVD tests, a faint or absent test line (false non-reactive) may occur in specimens containing high antibody densities; the prozone effect. In order to obtain a definitive result, all clinical and laboratory findings should be evaluated.

Internal quality control

The Bioline™ HCV test device has 2 pre-coated lines on the surface of the test: "T" (test line) and "C" (control line). Neither the test line nor the control line is visible in the result window before applying a specimen. The control line is used for procedural control and shows only that the diluent has been applied successfully and that the active ingredients of the main components on the strip are functional, but it is not an assurance that the specimen has been properly applied; it is not a reactive specimen control.

Performance characteristics

Bioline™ HCV test kit has been evaluated in 3 different sites as below. The results of individual laboratories may vary from these data because the results can be unique to the population it serves depending upon geographical, patient, dietary, environmental and other factors.

ENGLISH