For in vitro diagnostic use only

STANDARD Q° HCV A

STANDARD Q HCV Ab Rapid Test

PLEASE READ COMPLETE KIT INSERT CAREFULLY BEFORE YOU PERFORM THE TEST



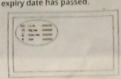


[Preparation]

Carefully read the instruction for using the STANDARD Q HCV Ab Test.

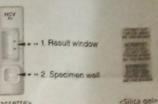


2 Look at the expiry date at the back of the cassette package. Use another lot, if expiry date has passed.



3 Open the cassette package & check for the cassette & silica gel.

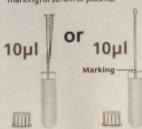




[Test Procedure]

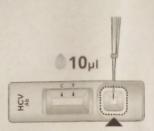
1. For Serum or Plasma specimen

Specimen Collection Using a micropipette or specimen transfer device collect 10µl (till marking) of serum or plasma.



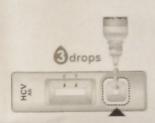
2 Specimen Addition

Add the collected serum or plasma to the specimen well of the cassette.



3 Buffer Addition

Add 3 drops of buffer into specimen well of the cassette

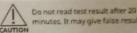


4 Reading Time

Read the test results after 5 minutes. The test can be read up to 20 minutes.



After 5 mins



2. For Whole Blood specimen

1 Specimen Collection

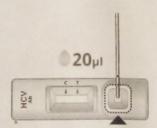
Collect 20µl of whole blood by using a micropipette or collect two times 10µl of whole blood till the marking of specimen transfer device



2x10µI=20µI 20µ1

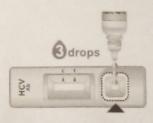
2 Specimen Addition

Add the collected whole blood to the specimen well of the cassette.



3 Buffer Addition

Add 3 drops of buffer into specimen well of the cassette.



4 Reading Time

Read the test results after 5 minutes. The test can be read up to 20 minutes.

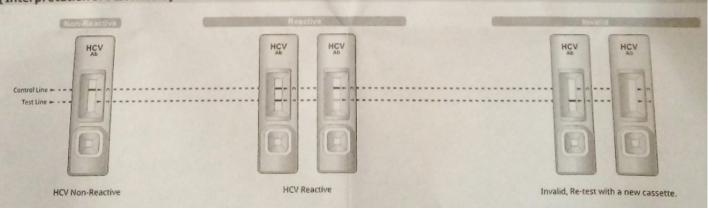


After 5 mins Can be read Up to 20 mins



Do not read test result after 20 minutes. It may give false resul

[Interpretation of Test Result]



- 1. A colored band will appear in the top section of the result window to show that the test is working properly. This band is the control line (C).
- 2. A colored band will appear in the lower section of the result window. This band is the test line (T).
- 3. Even if the control line/test line is faint, or the test line is not uniform, the test should be considered to be performed properly and the test result should be interpreted as a reactive result.
 - * Reactive results should be considered in conjunction with the clinical history and other data available to the physician.

EXPLANATION AND SUMMARY

STANDARD Q HCV Ab Test is a rapid chromatographic immunoassay for the qualitative detection of specific antibodies to HCV present in human serum, plasma or whole blood. This test is for in vitro professional diagnostic use and intended as an aid to early diagnosis of NCV infection in patient with clinical symptoms with HCV infection. It provides intended as an aid to early diagnosis of NCV infection in patient with clinical symptoms with HCV infection. It provides only an intial screening test result. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of HCV infection.

FTANDARD Q HCV Ab Test contains two pre-coated lines, "C" (Control line), "T"(Test line) on the surface of the strategy of the control line and test line in the result window are not visible before applying any introceilulose membrane. Both the control line and test line in the result window are not visible before applying any introceilulose membrane. Both the strategy of the str

| Components | | |
|------------------------|--------------------------|--|
| Cassette Buffer Bottle | Specimen transfer device | |
| | Instruction for use | |

Store the RDT Box at room temperature, 2-40°C / 36-104°F out of direct sunlight. Materials provided are stable until the expiry date printed on the RDT box. DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

- 1. Collect the whole blood into the commercially available plain tube NOT containing anti-coagulant such as heparin or EDTA by venipuncture and leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.

 2. If serum in the plain tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -20°C/3-4°F.

 3. It should be brought to room temperature prior to use.

[Plasma]

- Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin or EDTA by venipuncture and centrifuge blood to get plasma specimen.

 If plasma in an anti-coagulant tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below-20°C/-4°F.

 It should be brought to room temperature prior to use.

- [Whole Blood]
 Capillary whole blood

- Capillary whole blood
 Capillary whole blood should be collected aseptically by fingerup.
 Clean the area to be lanced with an alcohol swab.
 Squeeze the end of the fingerup and pierce with a sterile lancet.
 Collect the capillary whole blood till the marking of the specimen transfer device for the testing.
 The capillary whole blood must be tested immediately after collection.

- Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin or EDTA by venipuncture.

 If venous whole blood in an anti-coagulant tube is stored in a refrigerator at 2-8°C/ 36-46°F, the specimen can be used for testing within 1-2 day after collection.

 Do not use hemolyzed blood specimen.



- Anticoagulants such as heparin or EDTA do not affect the test result.
 As known relevant interference, haemolytic specimen, rheumatoid factors-contained specimen and lipaemic, icteric specimen can lead to impair the test results.
 Use separate disposable materials for each specimen in order to avoid cross-contamination which can cause erroneous results.

TEST PROCEDURE

- [Preparation]
 1. Carefully read instructions for using the STANDARD Q HCV Ab Test.
 2. Look at the expiry date at the back of the cassette package. Use another lot, if expiry date has passed.
 3. Allow the RDT kit to come at room temperature before opening the cassette package.
 4. Open the cassette package & check for the cassette & silica get.
 5. Methods for following steps can be changed depending on the specimen or specimen transfer device.

- For serum or plasma specimen

 Using a micropropette or specimen transfer device collect 10µl (till the marking) of serum or plasma.

 Add 3 drops of buffer into the specimen well of the cassette.

 Add 3 drops of buffer into the specimen well of the cassette.

 Read the test results after 5 minutes. Test can be read up to 20 minutes.

- Collect 20µl of whole blood by using a micropipette or collect two times 10µl of whole blood till the marking of specimen transfer device.

 Add the collected whole blood to the specimen well of the cassette.

 Add 3 drops of buffer into the specimen well of the cassette.

 Add 3 drops of buffer into the specimen well of the cassette.



· Do not read test results after 20 minutes. It may give false results.

INTERPRETATION OF TEST RESULTS

- Invalid: If the control band (°C° Control line) is not visible within the result window, the result is considered invalid. The directions may not have been followed correctly. In such case, it is recommended to retest the specimen with a new cassette.



- Even if the control line/test line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a reactive result.
 Reactive result should be considered in conjunction with the clinical history and other data available to the physician.

LIMITATION OF TEST

- 1. The test should be used for the detection of HCV antibodies in human serum, plasma or whole blood specimen.
 2. Neither the quantitative value nor the rate of HCV antibodies concentration can be determined by this qualitative test.
 3. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
 4. A non-retartive test result may occur if the level of extracted antibody in a specimen is below the sensitivity of the test or if a poor-quality specimen is obtained.
 5. For more securacy of immune status, additional following sestion using other laboration must be sensitived.
- 5. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recome
 6. The test result must always be evaluated with other data available to the physician.

QUALITY CONTROL

STANDARD Q HCV Ab Kit has test line and control line on the surface of each cassette. All the test line and control line in result window are not visible before applying specimen. The control line is used for procedural control. It will appear if the test has been performed correctly and the reagents are functional. If it does not appear, the test results are not valid and test has been performed correctly and the reagents are functional. If it does not appear, the test results are not valid and the test must be repeated. In addition, good laboratory practice recommends the daily use of control materials to confirm the test procedure and to verify proper test performance.

PERFORMANCE CHARACTERISTICS

e performance characteristics of STANDARD Q HCV Ab is found

Sensitivity - 100% | Specificity - 99.74%

WARNINGS AND PRECAUTIONS

- 1. Do not resuse the kit.
 2. Do not use the kit.
 3. Do not the cassette package is damaged or the seal is broken.
 3. Do not use the buffer bottle of another lot.
 4. Do not smoke, dinn's or earth-life handling specimen.
 5. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
 6. Clean up spills thoroughly using an appropriate disinfectant.
 7. Handle all specimens as if they contain infectious agents.
 8. Observe established precautions against microbiological hazards throughout testing procedures.
 9. Dispose off all specimens and materials used to perform the test as bio-hazard waste. Liberatory chemical and bio-hazard waster must be handled and discarded in accordance with all local, state, and national regulations.
 10. Silica gel in cassette packaging is to absorb moisture and prevent humidity from affecting products.
 11. Buffer contain sodium acide as a preservative. If these materials are to be disposed off frough sink or other common plumbing system, flush with generous water to prevent accumulation of potentially explosive compound.
 12. For in vitro diagnostic use only.
 13. Do not use the kit contents beyond the expiry date printed outside the box.
 14. Immediately perform the test after removing the test device from the cassette package.
 15. Discard the cassette immediately after reading result.

BIBLIOGRAPHY

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Product Disclaimer
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