Kwiq-Test HIV 1/2 Serum/Plasma/Whole Blood Test

Product codes	M001-C0001	M001-C0002
Pouch sealed tests	25	40
Single-use capillary tubes	25	40
Single-use sterile lancets	25	40
Alcohol swabs	25	40
Assay buffer	One 5ml bottle	Two 5ml bottles
Instructions for use	1	1

INTENDED USE

Kwiq-Test, HIV 1/2 Serum/Plasma/Whole Blood Test is an in vitro, visually read, qualitative immunochromatographic rapid diagnostic test for detection of antibodies against Human Immunodeficiency Virus (HIV)Types 1 & 2 in Human Serum, Plasma, finger stick whole blood or Venous Whole Blood. It is used as a screening point-of-care test to aid in the diagnosis of HIV type 1 & 2 infection.

It is not intended for use in plasma, blood, cell or tissue donors.

It is intended for professional use only.

For in vitro diagnostic use only.

PRINCIPLE OF THE PROCEDURE

Kwiq-Test HIV 1/2 Serum/Plasma/Whole Blood Test is a rapid immunochromatographic direct binding test for qualitative detection of antibodies to HIV-1 and HIV-2 in human venous whole blood, fingerstick whole blood, plasma and serum samples in the diagnosis of HIV infection. The test employs a unique combination of a specific antibody binding protein conjugated to colloidal dye particles and HIV-1 and HIV-2 antigens bound to the solid phase membrane. Kwiq-Test HIV 1/2 Serum/Plasma/Whole Blood Test adopts a double antigen sandwich method. When the specimen is applied to the sample well of the device, it is absorbed into the nitrocellulose membrane by capillary action. Test specific buffer is also applied to the buffer well to facilitate the lateral flow of the specimen and test reagents, and promote binding of the antibodies to the antigen. The sample and buffer mixture reconstitutes and mixes with pre-coated antigen-dye conjugate and migrates along the test strip by capillary action.

If present, HIV-1 / or HIV-2 antibodies bind to the pre-coated antigen-dye conjugate on the nitrocellulose membrane. When the HIV antibody levels are at or above the detection limit of the test, the dye conjugated-immune complex migrates on the nitrocellulose membrane and is captured by the antigens immobilized in the TEST (T) area producing a red-pink colored line that indicates a positive result.

If neither HIV-1 nor HIV-2 antibodies are present or their levels are below the detection limit of the assay, no colored line will form in the TEST region (T) of the device.

To serve as a control, a red-pink colored line forms in the CONTROL (C) area containing rabbit immunoglobin G (IgG) antigens. This procedural control serves to demonstrate that the specimen and reagents have been properly applied and have migrated through the device.

WARNINGS

For In-Vitro Diagnostic use

1. Read and understand the instructions for use completely before using this assay. Follow the instructions carefully as not doing so may result in inaccurate test results.
2. Do not use any other liquid other than the buffer provided during the assay.
3. Use the test device with the specimen types that are instructed to be used as using other specimen types that are not instructed will result in inaccurate results.
4. This test assay should be performed at room temperature between 10°C-30°C. If stored in a refrigerator, ensure that all components return to room temperature before they are put to use.
5. Ensure that the test device is removed from the foil pouch only at the time of use. Do not leave unused for more than one hour.
6. Once the test device is removed from the foil pouch and not used, it should be discarded as the test strip is sensitive to humidity and thus the results obtained may be inaccurate.
7. Do not use the kit contents after the expiry date has been reached.
8. Ensure that the fingers of the subject under test are fully dry before picking off the sample.
9. Ensure to read the results in a well-lit room to avoid inaccurate reading of the results.
10. Results should be read not earlier than 15 minutes and not later than 30 minutes from the time of buffer addition as doing so will result in erroneous results.
11. Failure to add the sample and the buffer in the correct order as stated in the procedure shall result in erroneous results.
12. Specimens from individuals infected with HIV-1/2 who are receiving antiretroviral (ART) therapy may produce false negative test results.
13. Specimens from individuals with Epstein-Barr Virus may give false positive test results.
14. Do not interchange, neither pool nor use the buffers from other lots as this may interfere with the test results.

PRECAUTIONS

Safety precautions

1. Handle the samples and the materials that are in contact with the sample as infectious.
2. Ensure to put on protective equipment like disposable gloves, laboratory coats when handling patients and their samples.
3. Properly dispose of the used devices and other materials used during the testing process carefully into disposable biohazard bags. The lancets shall be put in safety boxes before disposal. Materials should be autoclaved at 121°C for 1 hour and disposable materials may be incinerated. All this should be done as per the standard guidelines for disposal of infectious waste.
4. Clean and disinfect all spills using 0.5% sodium hypochlorite or any other appropriate disinfectant.

Handling precautions

5. Each test kit, disposable capillary tube and lancet are for single-use only.
6. If the desiccant is missing or the orange-colored desiccant particles have turned green do not use. Discard the test device and get a new one.
7. Ensure to check the expiry date before using the test device to avoid using the devices beyond the expiry date.
8. Open only the **red cap** of the diluent buffer.

COMPONENTS OF THE KWIQ TEST KIT

A. Kit components:

1. Foil pouch containing a single-use Kwiq test device, and a desiccant that can easily be removed by tearing the pouch at the notch.
2. Ziplock bag containing single-use capillary tubes.
3. Ziplock bag containing single-use sterile safety lancets.
4. Ziplock bag containing alcohol swabs.
5. HIV 1/2 buffer (5ml).
6. Instructions for use insert.

B. Reactive ingredients of main components

One test strip includes: Gold conjugate (HIV gp41/gp36 fusion recombinant antigen-gold colloid and rabbit IgG polyclonal antibody gold colloid), the test line has HIV gp41 recombinant antigen and HIV gp36 recombinant antigen) and the control line has Goat anti rabbit IgG polyclonal antibody).

Materials required but not provided

1. Timer.
2. Calibrated precision pipettes for use during testing of samples collected in blood collection tubes other than finger-stick testing.
3. An appropriate biohazard disposal container/ waste bin.
4. Protective gloves.
5. Sterile adhesive bandages.
6. Blood collection tubes for specimens rather than finger-stick specimens.
7. Centrifuge for separating serum/ plasma from whole blood.
8. Cotton Wool

IVD STORAGE, OPERATING CONDITIONS AND STABILITY

The kit and unused buffer must be stored at 2°C to 30°C before expiration date; the opened buffer should be stored at 2°C to 30°C , but not for more than 8 weeks .

Use the kit under the condition of humidity from 20% to 90% and the temperature from 10°C to 30°C.

Use the kit within 1 hour once the pouch is opened.

Keep away from sunlight, moisture and heat.

Do not freeze.

SPECIMEN COLLECTION AND STORAGE

Finger stick whole blood specimens

1. Clean the area of the fingertip to be lanced with an alcohol pad. Allow the finger to dry thoroughly.
2. Using a sterile lancet, puncture the lateral side of the fingertip. Apply gentle pressure beside the point of the puncture. Wipe away the first drop of blood with a sterile cotton swab.
3. Allow a new drop of blood to form. If blood flow is inadequate, the subject's finger may have to be gently massaged at the finger base to produce a droplet of sufficient volume. Avoid squeezing the fingertip to accelerate bleeding as this may dilute the blood with excess interstitial fluid.
4. Draw 10 microliter (µL) of finger blood with a capillary tube. Finger-stick whole blood specimens must be tested immediately.

Venous whole blood specimens

1. Using a standard phlebotomy procedure, collect a venous whole blood specimen using a blood collection tube containing suitable anticoagulant(containing EDTA, Sodium citrate or heparin).
2. It is recommended that specimens should be tested immediately. Venous whole blood specimens may be stored at room temperature (10°C - 30°C) for up to 4 hours before testing. If the specimen is not tested immediately, they should be stored at 2°C - 8°C for up to 7 days of collection. It is not suitable to test the whole blood samples which have been stored at 2°C - 8°C for more than 7 days.

Serum and plasma specimens

1. Using standard phlebotomy procedure, collect venous whole blood specimen using a blood collection tube. If you need to collect plasma, please use a blood collection tube which contains suitable anticoagulant (EDTA, heparin, or sodium citrate).
2. Centrifuge whole blood and separate the serum/ plasma from red blood cells as soon as possible to avoid haemolysis.
3. Serum and plasma specimens may be stored at room temperature (10°C - 30°C) for up to 4 hours before testing. If testing will not be performed within 4 hours of sample collection, the specimens should be stored at 2°C - 8°C within 7 days of collection. If testing is delayed for more than 7 days, the specimens should be frozen (-20°C or colder) for a maximum of 6 months. Bring specimens to room temperature (10°C - 30°C) before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freeze/thaw cycles. Specimens that have been frozen and thawed more than 5 times cannot be used. Only clear non-haemolysed specimens should be used.

TEST PROCEDURE

Kit component preparation

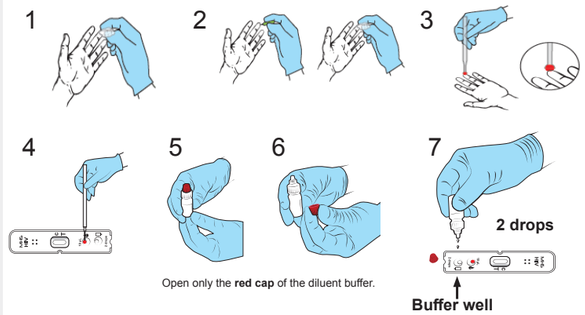
Please read the information in this IFU before using the IVD.

Bring all specimens and devices to room temperature (10°C - 30°C) before testing. When ready to test, remove the test cassette from the aluminum foil pouch by tearing at the notch and place it on a flat dry surface. Label the device with specimen ID number.

Note: Ensure that the pouch contains a desiccant. Do not use the test cassette in case the desiccant is missing or the orange-colored desiccant particles have turned green.

For finger stick whole blood,

1. Draw 10 µL fingerstick whole blood specimen with a capillary tube.
2. Slowly add it to the sample well, then add 2 drops of the buffer to the buffer well.
3. Read the test result between 15 and 30 minutes after the addition of the buffer. Do not read test results before 15 minutes and after 30 minutes.



Open only the **red cap** of the diluent buffer.

For serum, plasma or whole blood specimens

4. Using a precision pipette with a disposable tip, apply 10µL of the sample into the sample well
5. Add two drops of the buffer to the buffer well.
6. Read the test result between 15 and 30 minutes after the addition of the buffer. Do not read test results before 15 minutes and after 30 minutes.

INTERPRETATION OF RESULTS

Positive Result

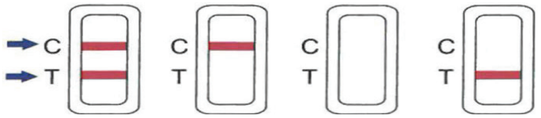
Two visible red-pink bands appear, one in the Test (T) area and one in the Control (C) area.
A positive result indicates that the concentration of HIV1/2 antibodies in the sample is equal to or higher than the detection limit of the test.

Negative Result

One visible red-pink band appearing in the Control (C) area, with no band appearing in the Test (T) area indicates a Non-reactive Test Result. A negative result indicates that the concentration of HIV 1/2 antibodies in the sample is below the detection limit of the test.

Invalid Result

There is no visible red-pink line at all, or there is a visible line only in the Test (T) area but not in the Control(C) area. Repeat with new test kit. If test still fails, please contact the distributor or the store where you bought the product.



LIMITATIONS OF THE PROCEDURE

1. The kit is designed to detect antibodies against HIV-1 and HIV-2 in human serum, plasma and whole blood.
2. The kit is a qualitative assay and is not designed to determine the quantitative concentration of HIV 1/2 antibodies.
3. For a reactive sample, the intensity of the T line does not necessarily correlate with the titre of the antibody in the specimen.
4. The presence of a control line means only that liquid has flowed correctly. The control line will appear irrespective of whether a specimen is reactive or non-reactive.
5. As it is with any diagnostic procedure, a confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated.
6. The kit must be used in accordance with the instructions in this product insert to obtain accurate results.
7. A negative result with Kwiq-Test, HIV 1/2 Serum/Plasma/Whole blood Test does not exclude the possibility of infection with HIV. A false negative result may occur in the following circumstances;
   - Recent infection. Antibody response to a recent exposure may take several months to reach detectable levels.
   - The test procedure has not been correctly followed.
   - Antibodies to a variant strain of HIV1/2 in the patient do not react with specific antigens utilized in the assay configuration.
   - Improper specimen handling.
   - Failure to add sample.
8. A person who has antibodies to HIV-1 or HIV-2 is presumed to be infected with the virus, except that a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV. Clinical correlation is indicated with appropriate counselling, medical evaluation and possible additional testing to decide whether a diagnosis of HIV infection is accurate.
9. The kit is not evaluated for use in Neonates.

TROUBLE SHOOTING

1. Buffer of less than 2 drops or more than 3 drops may cause incorrect results.
2. Specimen less than 5µl or more than 15µl may cause incorrect results.
3. The test result will be incorrect when the specimen and buffer are added in the wrong position or sequence

PERFORMANCE CHARACTERISTICS

1. Analytical performance Study-Interfering substances

Summary of test results for determination of analytical specificity with potentially interfering substances.

A. Specimens of HIV-1 Positive

Potentially interfering substances	Number	Number of erroneous result	
		Not spiked with anti-HIV Positive specimen	Spiked with anti-HIV Positive specimen
Alcohol	6	0	0
Haemoglobin	4	0	0
Direct bilirubin	7	0	0
Total bilirubin	17	0	0
Triglyceride	17	0	0
High-cholesterol	9	0	0
Low density Lipoprotein	15	0	0
Rheumatoid factor	25	0	0
IgM gammopathies	10	0	0
IgG gammopathies	2	0	0
Pregnant women	31	0	0
Systemic lupus erythematosus(SLE)	8	0	0
Anti-nuclear antibodies	8	0	0
Anti-escherichia coli	2	0	0
Total	161	0	0

2. Analytical performance Study-Cross reactivity

Summary of test results for determination of analytical specificity with potentially cross-reacting unrelated infections and diseases.

Potentially cross-reacting substance	Number	Number of erroneous result
Malaria	27	0
Epstein-Barr virus immunoglobulin (EBV IgM) 1	65	2
Influenza antibody	13	0
Cytomegalovirus Immunoglobulin M (CMV IgM)	5	0
Syphilis	5	0
Herpes Simplex Virus (HSV)	5	0
Anti-HBc	15	0
Anti-HBs	15	0
Anti-HCV	15	0
Anti HTLV	10	0
Anti-HEV	10	0
Total	185	2

3. Analytical performance Study-Analytical sensitivity

A total of 45 HIV seroconversion panels were tested, 25 of which were tested with product development partner and 20 were tested by a third party institution. Among the 25 seroconversion panels tested with product development partner with a commercially available WHO prequalified HIV ELISA reagent as a reference assay, HIV antibody in 6 panels was detected by Kwiq-Test HIV 1/2 Serum/Plasma/Whole blood Test earlier than that by the ELISA; HIV antibody in 2 panels was detected by Kwiq-Test HIV 1/2 Serum/Plasma/Whole blood Test later than that by the ELISA; and HIV antibody in 17 panels was detected by both assays at the same bleeding.

For the 20 HIV Seroconversion panels tested by the third party institution, 4 CE marked HIV ELISA reagents were set as a reference assay. From the 111 Seroconversion panel members, the Kwiq-Test HIV 1/2 Serum/Plasma/Whole blood Test detected 18 samples more than the least sensitive CE marked antibody test.

4. Analytical performance study HIV-1 subtypes positive specimens

50 specimens with various subtypes (10 specimens from each subtypes A1, B, C, CRF02_AG and G) were tested with product development partner. 40 specimens with various subtypes were tested by a third-party institution including 3 specimens for each of the following subtypes: C, CRF01_AE, CRF01_AG, CRF06_cpx, CRF36_cpx, D, G, group O, H, J and K, 2 specimens for subtypes A, F1 and F2 and 1 specimen for subtype A1.

Kwiq-Test HIV 1/2 Serum/Plasma/Whole blood Test can detect HIV 1/2 antibodies and the following subtypes of HIV-1 antibodies: Group O, subtype A, subtype A1, subtype B, subtype C, subtype D, subtype F1, subtype F2, subtype H, subtype J, subtype K, subtype G, CRF01_AE, CRF01_AG, CRF06_cpx and CRF36_cpx.

5. Clinical performance study – Diagnostic sensitivity

Summary of results of clinical study to determine diagnostic sensitivity

Specimen type	Number of specimens	False negative	Sensitivity	95% confidence interval
Serum	456	0	100%	(99.18, 100)
Plasma	620	0	100%	(99.38, 100)
Whole venous blood	100	0	100%	(99.30, 100)
Total	1176	0	100%	(99.67, 100)

B. Specimens of HIV-2 Positive

Specimens type	Number of specimens	False negatives	Sensitivity	95% confidence interval
Plasma	100	0	100%	(96.30, 100)

6.0. Clinical performance study – Diagnostic specificity

Summary of results of clinical study to determine diagnostic specificity

Specimen type	Number of specimens	False positive	Specificity	95% confidence interval
Serum	331	0	100%	(98.85, 100)
Plasma	1904	1	99.95%	(99.70, 99.99)
Whole venous blood	500	0	100%	(99.24, 100)
Total	2735	1	99.96%	(99.79, 99.99)

LIST OF REFERENCES

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SYMBOL KEY

REF	Catalogue number	LOT	Batch code
	Manufacturer		Use-by date
	Date of manufacture		Keep Dry
	Temperature limit		Caution
	Consult *instructions for use*		*Do not re-use*
	Keep away from sunlight		
	Contains sufficient for <*n*> tests		
IVD	In vitro diagnostic *medical device*		
	Do not use if package is damaged and consult *instructions for use*		

Microhaem Scientifics and Medical Supplies Ltd (MHS)
Plot 16, A-C, Martyrs' Way, Ntinda, Kampala, Uganda
Tel: +256393246401
Website: www.microhaem.co.ug

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