World Health Organization

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# WHO list of prequalified in vitro diagnostic products

**RoW: Rest of the world**. Regulatory version applied to products not approved by stringent/mature NRAs or not regulated

Last update: 20 November 2023

| Year prequalified | Type of assay | Product name | Product code(s) | Regulatory version | Manufacturer | Manufacturing site(s) | Packaging |
|---|---|---|---|---|---|---|---|
| 2019 | Malaria RDT | #AdvDx Malaria Pf Rapid Malaria Ag Detection Test | 00-DKM-RK-MAL-ADX-004-001,<br>00-DKM-RK-MAL-ADX-004-025,<br>00-DKM-RK-MAL-ADX-004-010, and<br>00-DKM-RK-MAL-ADX-004-050 | RoW | Advy Chemical Pvt Ltd., | Plot No.A-334,336,338 & A-337 & 339<br>Road no. 25 & 26, Wagle industial Estate<br>Thane 400 604<br>India | 1 T/kit,<br>10 T/kit,<br>25 T/kit,<br>50 T/kit |
| 2019 | Malaria RDT | # NxTek Eliminate Malaria Pf and<br><br>and NxTek Malaria Pf | 05FK140;<br>05FK141;<br>05FK142;<br>05FK143 | CE-marked | Abbott Diagnostics Korea Inc | **site 1:** 46, Hagal-ro 15 beongil,<br>Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea<br>**site 2:** 65, Borahagal-ro,<br>Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of | 25T/Kit;<br>25T/Kit;<br>1T/kit x 25 each;<br>1T/kit x 25 each |
| 2019 | HIV NAT | m-PIMA HIV-1/2 VL | 27015-W50 | RoW | Abbott Rapid Diagnostics Jena GmbH | Orlaweg 1, D-07743 Jena, Germany | 50 cartridges/kit |
| 2018 | Malaria RDT | First Response Malaria Antigen P. *falciparum* (HRP2) Card Test | PI13FRC25s;<br>PI13FRC10s;<br>PI13FRC25;<br>PI13FRC30 | RoW | Premier Medical Corporation Limited | **site 1:** A1-302, GIDC, Sarigam 396 155, Valsad, Gujarat, India;<br>**site 2:** 32-35A, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman 396215, India | 25 × single kit;<br>10 × single kit;<br>25 × multi kit;<br>30 × multi kit |
| 2018 | Malaria RDT | First Response Malaria Ag. P.f. / P.v. Card Test | PI19FRC10s;<br>PI19FRC25s;<br>PI19FRC30;<br>PI19FRC25 | RoW | Premier Medical Corporation Limited | **site 1**: A1-302, GIDC, Sarigam 396 155, Valsad, Gujarat, India;<br>**site 2**: 32-35A, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman 396215, India | 10 × single test;<br>25 × single test;<br>30 × multi test;<br>25 × multi test |
| 2018 | Malaria RDT | Bioline Malaria Ag P.f/P.f/P.v | 05FK120;<br>05FK123 | CE-marked | Abbott Diagnostics Korea Inc | 65 Borahagal-ro, Giheung-gu, Yongin-si, Geonggi-do, South Korea | 25T/kit;<br>1T/kit |
| 2018 | HIV RDT for self-testing | INSTI HIV Self Test | 90-1071 | RoW | bioLytical Laboratories Inc. | Richmond, British Columbia, Canada | 1T/kit |
| 2018 | HIV RDT | One Step HIV1/2 Whole Blood/Serum/Plasma Test | W006-C4P2,<br>W006-P0045,<br>W006-P0046,<br>W006-P0047,<br>W006-P0048,<br>W006-C4P2-F, | RoW | Guangzhou Wondfo Biotech Co., Ltd | 8 Lizhishan Road, Science City, Luogang District, Guangzhou, 510663, Republic of China | 25T/kit;<br>25T/kit;<br>25T/kit;<br>25T/kit;<br>25T/kit;<br>40T/kit; |
| 2018 | Malaria RDT | One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag | MFLRPD-02;<br>MFLRPD-03;<br>MFLRPD-04;<br>MFLRPD-05 | CE-marked | Meril Diagnostics Pvt. Ltd. | D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi 396191, Gujarat, India | 30T/kit;<br>25T/kit;<br>50T/kit;<br>10 T/kit. |

# One Step HIV1/2 Whole Blood/Serum/Plasma Test

## Catalog No.

W006-C4P2 (25Tests)
W006-P0045 (25Tests)
W006-P0046 (25Tests)
W006-P0047 (25Tests)
W006-P0048 (25Tests)
W006-C4P2-F(40tests)
W006-P0049 (40Tests)
W006-P0050 (40Tests)
W006-P0051 (40Tests)
W006-P0052 (40Tests)

## INTENDED USE

Wondfo® One Step HIV 1/2 Whole Blood/Serum/Plasma Test is intended for use by trained users(in either laboratory or point-of-care settings), and is a qualitative, screening, in vitro diagnostic test for detection of HIV 1/2 antibodies in human venous whole blood, fingerstick whole blood, serum or plasma, aid to diagnosis of HIV infection.

## SUMMARY AND EXPLANATION OF THE TEST

HIV (human immunodeficiency virus) is the pathogen of AIDS (acquired immunodeficiency syndrome). HIV belongs to Retroviridae genus Lentivirus family, and there are two groups of HIV, HIV-1 and HIV-2. HIV-1 is highly mutagenic and can be divided into 9 subtypes by the mutations in its membrane protein, which are A, B, C, D, E, F, G, H and O. HIV-2 has 60% nucleotide acid homology with HIV-1, but they are different in their ability of infection, HIV-1 is the most prevailing virus strain. Once infected, it mutates quickly and has bad prognosis. HIV-2 has a longer latent period, and relative weaker in its pathogenesis.



Wondfo® One Step HIV 1/2 Whole Blood/Serum/Plasma Test is a 3rd generation HIV immunoassay. The design of 3rd generation assays allows the detection of HIV specific IgG as well as IgM, which may occur early in infection.

## PRINCIPLE OF THE PROCEDURE

Wondfo One Step HIV1/2 Whole Blood/Serum/Plasma Test is a rapid immunochromatographic direct binding test for the visual detection of HIV antibodies in venous whole blood, fingerstick whole blood, serum or plasma samples in the diagnosis of HIV infection. Wondfo One Step HIV1/2 Whole Blood/Serum/Plasma Test adopts double antigen sandwich method. When the specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with the antigen-dye conjugate, and flows across the HIV antigen pre-coated membrane.

When the HIV antibody levels are at or above the detection limit of the test, HIV antibodies in the specimen bind to the antigen-dye conjugate and are captured by antigen immobilized in the test region (T) of the device. This produces a colored test band and indicates a positive result.

If no HIV antibodies are present or below the detection limit of the assay, no colored band will be visible in the test region (T) of the device. This indicates a negative result.

To serve as a procedure control, a colored line will appear at the control region (C), if the test has been performed properly.

## WARNINGS AND PRECAUTIONS

1. This assay has been evaluated on EDTA, heparin, and sodium citrate. Other anticoagulants are excluded.
2. Read the Instructions for Use before using this product. The instructions must be followed carefully as not doing so may result in inaccurate results.
3. Wear protective clothing such as laboratory coat, safety glasses and disposable gloves when handling specimens.
4. Wash hands thoroughly after use.Not intended for use in screening blood and tissue donors. This assay has not been evaluated for neonate or cord blood specimens.
5. This kit is for *in vitro* diagnosis of the infection of HIV only, this assay will not provide a diagnosis for any other disease.
6. Do not smoke, eat, drink, apply cosmetics or handle contact lenses in areas in which specimens are handled.
7. All specimens should be treated as potentially infectious.
8. EBV IgM positive specimens may cause erroneous results.
9. Discard test cassette, dropper, desiccant pouch after first useThe test can not be used more than once.
10. Cap and tightly the opened buffer after using.
11. Do not use the kit beyond the expiration date.
12. Do not use the kit if the pouch is punctured or not well sealed. Do not mix buffer /test devices from different kit lots.
13. Keep out of the reach of children.
14. All specimens and used-devices have infectious risks. The disposal process must follow the local infectious disposal law or laboratory rules.

## CONTENT OF THE KIT

**A. Kit components**

Each individual sealed pouch contains one test cassette, one dropper and one desiccant pouch (for storage purposes only). Each test cassette contains one plastic cassette and one test strip.

The different article Number are as follows:



| Components / Catalog No. | Pouch (pcs) | Buffer (bottle) | Instruction (pcs) | Alcohol swab (pcs) | Sterile lancet (pcs) | Safety lancet (pcs) | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | 18G | 21G | 23G |
| W006-C4P2(25 Tests/Kit) | 25 | 1 | 1 | - | - | - | - | - |
| W006-P0045 (25 Tests/Kit) | 25 | 1 | 1 | 25 | 25 | - | - | - |
| W006-P0046 (25 Tests/Kit) | 25 | 1 | 1 | 25 | - | 25 | - | - |
| W006-P0047 (25 Tests/Kit) | 25 | 1 | 1 | 25 | - | - | 25 | - |
| W006-P0048 (25 Tests/Kit) | 25 | 1 | 1 | 25 | - | - | - | 25 |
| W006-C4P2-F(40 Tests/Kit) | 40 | 2 | 1 | - | - | - | - | - |
| W006-P0049 (40 Tests/Kit) | 40 | 2 | 1 | 40 | 40 | - | - | - |
| W006-P0050 (40 Tests/Kit) | 40 | 2 | 1 | 40 | - | 40 | - | - |
| W006-P0051 (40 Tests/Kit) | 40 | 2 | 1 | 40 | - | - | 40 | - |
| W006-P0052 (40 Tests/Kit) | 40 | 2 | 1 | 40 | - | - | - | 40 |

**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), Test line (HIV gp41 recombinant antigen and HIV gp36 recombinant antigen) and Control line (Goat anti rabbit IgG polyclonal antibody).

## MATERIALS REQUIRED BUT NOT PROVIDED

**For W006-C4P2(25 Tests/Kit) and W006-C4P2-F(40 Tests/Kit):**

1. Specimen collection containers
2. Sterile lancets
3. Alcohol Swabs
4. Centrifuge (for serum/plasma specimen only)
5. Timer
6. Protective gloves
7. Specimen and test waste container

**For W006-P0046、W006-P0047、W006-P0048、W006-P0050、W006-P0051 and W006-P0052:**

1. Specimen collection containers
2. Centrifuge (for serum/plasma specimen only)
3. Timer
4. Protective gloves
5. Specimen and test waste container



## STORAGE AND OPERATING CONDITIONS

1. The kit and the unused buffer must be stored at 2℃-30℃ before expiration date; the opened buffer should store at 2℃-30℃, no more than 8 weeks.
2. Use the kit within 1 hour once the pouch is opened.
3. Use the kit under the condition of the humidity from 20% to 90% and the temperature from 10℃ to 30℃.
4. Recap and store the Buffer vial in the original container after use.
5. Shelf-life of the test devices and the Buffer are 24 months from the manufacturing date.
6. Keep away from sunlight, moisture, and heat.
7. Do not freeze.

## COLLECTING AND PREPARING SPECIMENS

**Whole blood – Collected by venipuncture**

1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (containing EDTA, citrate, or heparin).
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature(10℃ to 30℃) within 4 hours. If the specimens are not tested immediately, they may be stored at 2℃-8℃for up to 7 days, only. It's not suitable to test the whole blood samples which have been stored at 2℃-8℃ for more than 7 days.

**Whole blood – Collected by fingerstick**

1. Clean the area to be lanced with an alcohol pad. Allow the finger to dry thoroughly.
2. Using a lancet, puncture the inside of the finger pad. Apply gentle pressure beside the point of the puncture. Wipe away the first drop of blood with a sterile swab. 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.
3. Draw 10 microliter (μL) of finger blood with a capillary tube.
4. Whole blood specimens collected by fingerstick should be tested immediately.



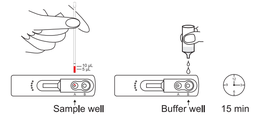
**Serum and Plasma**

1. Using standard phlebotomy procedure, collect a venipuncture 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 plasma from red blood cell as soon as possible to avoid hemolysis.
3. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature within 4 hours. Specimens should be stored at 2℃-8℃ if the test is to be run within 7 days of collection. If testing is delayed more than 7 days, the specimen should be frozen (-20℃ or colder).
   Bring specimens to room temperature(10℃ to 30℃) before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly(Not more than 5 times). Only clear, non-hemolyzed specimens can be used.

## TEST PROCEDURE

Equilibrate all specimens and the devices to room temperature (10℃～30℃) before testing.

1. Remove a test cassette from the foil pouch by tearing the notch and place it on a level surface.
2. Use the specimen of either serum, plasma, or whole blood (collected by venipuncture): Slowly add 10μL (the second mark line of the dropper) of specimen to the sample well A, and then add 2 drops of buffer to the buffer well B.
3. Use the specimen of whole blood (collected by fingerstick): collecting the specimen by capillary tube (not provided), slowly add 10μL of specimen to the sample well A, and then add 2 drops of buffer to the buffer well B.
4. Incubate the cassette at room temperature (10℃～30℃), and read the result after 15 minutes, but not more than 30 minutes. Reading the test before 15 minutes or after 30 minutes may cause false result.




## INTERPRETATION OF TEST RESULTS

**Positive Result**

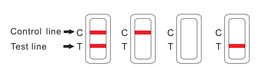
Rose-pink bands are visible in both the control region and the test region. A positive result indicates that the concentration of HIV1/2 antibodies in the sample is equal to or higher than the detection limit of the test.

**Negative Result**

A rose-pink band is visible in the control region. No color band appears in the test region. It indicates that the concentration of the HIV1/2 antibodies in the sample is below the detection limit of the test.

**Invalid Result**

No visible band at all, or there is a visible band only in the test region but not in the control region. Repeat with a new test kit. If test still fails, please contact the distributor or the store, where you bought the product, with the lot number.






## 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. It is not designed to determine the quantitative concentration of HIV antibodies.
3. The intensity of the T line does not necessarily correlate to the titer of antibody in the specimen.
4. The presence of the 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. A negative result with One Step HIV1/2 Whole Blood/Serum/Plasma 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.
7. 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 counseling, medical evaluation and possible additional testing to decide whether a diagnosis of HIV infection is accurate.

## TROUBLESHOOTING

1. Buffer of less than 2 drops or more than 3 drops may cause incorrect results.

2. Specimen less than 5μL (the first mark line of the dropper) or more than 15μL (the third mark line of the dropper) may cause incorrect results.
3. The test result will be incorrect when adding the specimen and buffer in wrong position or sequence.

## PERFORMANCE CHARACTERISTICS

**1. Analytical performance study - Interfering substances**

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

A. Specimens of HIV-1 positive

| Potentially interfering substance | 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 |
| Rheumatic 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 (ANA) | 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 speci- ficity: 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) | 5 | 2 |
| Epstein-Barr virus immunoglobulin(EBV IgM) | 60 | 0 |
| Influenza antibody | 13 | 0 |
| Cytomegalovirus immunoglobulin M(CMV IgM) | 5 | 0 |
| Syphilis | 5 | 0 |
| Herpes simples virus(HSV) | 5 | 0 |
| Anti-HBc | 15 | 0 |
| Ant-HBs | 15 | 0 |
| Anti-HCV | 15 | 0 |
| Anti-HTLV 1/2 | 15 | 0 |
| Anti-HEV | 10 | 0 |
| Total | 185 | 2 |

NOTE:
1. Testing in the third party Institute of Tropical Medicine
2. Testing in Guangzhou Wondfo Biotech Co.,Ltd.

**3. Analytical performance study - Analytical sensitivity**

A total of 45 HIV seroconversion panels were tested, 25 of which were tested by Wondfo and 20 were tested by a third party institution. Among the 25 HIV seroconversion panels tested by Wondfo with a commercially available WHO prequalified HIV ELISA reagent as reference assay, HIV antibody in 6 panels was detected by Wondfo One Step HIV1/2 Whole Blood/Serum/Plasma Test earlier than that by the ELISA; HIV antibody in 2 panels that detected by Wondfo One Step HIV1/2 Whole Blood/Serum/Plasma Test were later than that by the ELISA; and HIV antibody in 17 panels were 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 reference assay. From the 111 seroconversion panel members, the One Step HIV 1/2 Whole Blood/Serum/Plasma Test detected 18 samples more than the least sensitive CE marked antibody test and 4 samples less than the most sensitive CE marked antibody test.

**4. Analytical performance study - HIV-1 subtypes positive specimens**

The HIV-1 Worldwide Performance Panel, the WHO International Standard HIV (antibody), 1st International Panel (NIBSC code: 02/210) and 50 specimens with various subtypes (10 specimens for each of subtypes A1, B, C, CRF02_AG and G) were tested by Wondfo. And 40 specimens with various subtypes were tested by a third party institution, including 3 specimens for each of following subtypes: C, CRF01_AE, CRF02_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,
Wondfo One Step HIV1/2 Whole Blood/Serum/Plasma Test can detect HIV-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, CRF02_AG, CRF06_cpx, CRF36_cpx and CRF02-AG.

**5. Clinical performance study - Diagnostic sensitivity**

Summary of results of a clinical study to determine diagnostic sensitivity.

| Specimens type | No. 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% | (96.30, 100) |
| Total | 1176 | 0 | 100% | (99.67, 100) |



B. Specimens of HIV-2 positive

| Specimens type | No. of specimens | False negative | Sensitivity | 95% Confidence Interval |
|---|---|---|---|---|
| Plasma | 100 | 0 | 100% | (96.30, 100) |

**6. Clinical performance study - Diagnostic specificity**

Summary of results of a clinical study to determine diagnostic specificity.

| Specimens type | No. of specimens | False positive | Specificity | 95% Confidence Interval |
|---|---|---|---|---|
| Serum | 331 | 0 | 100.00% | (98.85, 100) |
| Plasma | 1904 | 1 | 99.95% | (99.70, 99.99) |
| Whole venous blood | 500 | 0 | 100.00% | (99.24, 100) |
| Total | 2735 | 1 | 99.96% | (99.79, 99.99) |

## LIST OF REFERENCES


1. Janssen R. S. etal. New testing strategy to detect early HIV-1 infection for use in incidence estimates and for clinical and prevention purposes. JAMA(1998) 280(1): 42-48.
2. CDC. Update: HIV Counseling and Testing using Rapid Tests United States,1995. MMWR 1998; 47(11).
3. Gale R. Burstein, Jonathan Pincus et al. A rapid review of rapid HIV antibody tests. Current Infectious Disease Reports, Volume 8, Number 2, March 2006,Pages 125-131.
4. Bernard M. Branson. State of the Art for Diagnosis of HIV Infection. Clinical Infectious Diseases 2007; 45: S221–S225.
5. Holm-Hansen C, Constantine NT, Haukenes G. Detection of antibodies to HIV in homologous sets of plasma,urine and oral mucosal transudate sample using rapid assays in Tanzania[J]. ClinDiagnVirol, 1993,1(4): 207-214.


## SYMBOLS KEY

| | | |
|---|---|---|
| IVD *In vitro diagnostic medical device* | Consult Instructions for Use | Expiry Date |
| Content sufficient for < n > tests | Date of manufacture YYYY-MM-(DD) | Keep dry |
| LOT Batch code | Temperature limit | Keep away from sunlight |
| Indicates the device manufacturer | Do not re-use | REF Product code/ Catalogue number |
| Caution | | |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Any complaints, questions, problems, suggestions or comments, please contact us by phone, e-mail or in writing.

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