# HIV 1/2 Rapid Test

## INSTRUCTION FOR USE

**REF PSHIV01/25, PSHIV01/40, PSHIV01/50, PSHIV01/100**

### INTENDED USE

**Phila•TEST™ HIV 1/2 Rapid Test** is intended for use by healthcare professionals and qualified laboratory personnel. It is a single use, qualitative lateral flow immunoassay for *in vitro* detection of antibodies to Human Immunodeficiency virus types 1 and 2 (HIV-1 and HIV-2) in whole blood, serum or plasma. The test is intended for use as a screening test to diagnose HIV infection by professional healthcare practitioners. All specimen tested positive with the **Phila•TEST™ HIV 1/2 Rapid Test** must be confirmed with alternative testing method(s) such as ELISA or PCR.

**Phila•TEST™ HIV 1/2 Rapid Test** is not intended for use to screen blood donors.

### TEST SUMMARY

The human immunodeficiency virus type 1 and 2 (HIV 1+2) are enveloped single stranded RNA viruses that cause acquired immunodeficiency syndrome (AIDS). The HIV virus attacks the CD4 cells of the body which help the immune system to fight infections.

Presence of specific HIV-1 and/or HIV-2 virus antibodies in blood, serum, or plasma indicates exposure to the HIV-1 and/or HIV-2 virus, and is of great value in clinical diagnosis. The **Phila•TEST™ HIV 1/2 Rapid Test** is a simple, visual, qualitative test that detects these antibodies in whole blood, serum or plasma. Based on immunochromatographic principles the test is cost effective, easy to perform and provides test results within 15 minutes.

### PRINCIPLE OF THE ASSAY

**Phila•TEST™ HIV 1/2 Rapid Test** is a lateral flow chromatographic immunoassay for the qualitative detection of HIV-1 and HIV-2 specific antibodies. The nitrocellulose membrane is coated with recombinant HIV-1 capture antigens on test line "1" and with recombinant HIV-2 capture antigens on test line "2". A control agent is immobilised at control line "C". The test is initiated by adding the specimen (whole blood, serum or plasma) and the supplied buffer to the sample well. The recombinant HIV-1 and HIV-2 antigens conjugated with colloidal gold nanoparticles bind to the HIV-1 and HIV-2 antibodies in the test sample. The conjugated antibody-antigen complex migrates across the nitrocellulose membrane where it attaches to the corresponding HIV-1 and HIV-2 antigens on the test lines. The resultant red lines indicates a positive result. A red line on the control zone will appear on the test kit irrespective of a positive or negative result to indicate the correct performance of the reagents of the test kit.

### MATERIALS PROVIDED

| Materials provided | PSHIV01/25 | PSHIV01/40 | PSHIV01/50 | PSHIV01/100 |
|---|---|---|---|---|
| Rapid test device pouch containing: 1 test device, 1 desiccant | 25 | 40 | 50 | 100 |
| Specimen transfer device | 25 | 40 | 50 | 100 |
| Disposable safety lancets | 25 | 40 | 50 | 100 |
| Alcohol swabs | 25 | 40 | 50 | 100 |
| Assay buffer (5ml) | 1 | 2 | 2 | 2 |
| Instruction for use | 1 | 1 | 1 | 1 |

**Note:** All materials provided other than the assay buffer and Instruction of Use are for single use only.

**Materials required but not provided:**

- Timer or stopwatch
- Disposable Gloves
- Absorbent paper or cloth
- Micropipette when using plasma
- Biohazard waste container

### HANDLING

The test devices should be stored between 2-30°C. Do not store the test kits in a freezer. Once opened from the foil pouch, the test should be used immediately. Use the buffer within 8 weeks of opening.

### WARNING AND PRECAUTIONS

- Handle all specimen as potentially infectious. Use disposable gloves while handling specimen and performing the assay.
- Apply biosafety precautions and dispose of potentially infectious material properly in proper biohazard waste containers after use.
- Avoid splashing.
- Clean up spills thoroughly using an appropriate disinfectant.
- Do not allow the tip of the assay buffer bottle to come into contact with the specimen as it may contaminate the assay buffer.
- When disposing of the assay buffer down a sink, flush with large quantities of water.
- Immediately dispose of the lancet into the sharps container after use.
- All positive tests must be confirmed using an alternative test method.
- For *in vitro* diagnostic use with whole blood, serum or plasma only.
- Read instructions carefully before performing the test as deviations from the instructions will invalidate the test results.
- Do not use the test kit if the pouch is damaged, the seal is broken or if the kit is beyond its expiration date.
- Do not re-use test strip or any other single use accessories.
- Do not combine reagents from different kit batch numbers.
- Do not eat, drink or smoke while handling specimens and carrying out the test.
- Do not eat the desiccant.
- Do not drink the assay buffer.
- Only use the assay buffer supplied with the test kit as other buffers will invalidate the results.
- The test is invalid if buffer is added to the test strip without any blood, even if a line is observed at (C).

### SPECIMEN COLLECTION AND STORAGE

**Phila•TEST™ HIV 1/2 Rapid Test** can be performed using whole blood (from fingerstick or venipuncture), serum or plasma.

**To collect Venous whole blood specimens:**

- Collect blood according to safe venipuncture procedures in a clean collection tube containing anti-coagulant EDTA, sodium citrate or heparin (not provided).
- If samples are not immediately tested, they should be stored at 2°C - 8°C for not more than 3 days.
- Do not use turbid or haemolysed samples
- Shake blood tube gently before use.

**To collect Serum specimens:**

- Collect blood according to safe venipuncture procedures in a collection tube containing no anti-coagulant (not provided).
- Leave to settle for 30 minutes for the blood to coagulated and then centrifuge at 3000rpm for 5 minutes to obtain serum supernatant.

**To collect Plasma specimens:**

- Collect blood according to safe venipuncture procedures in a clean collection tube containing anti-coagulant EDTA, sodium citrate or heparin (not provided).
- Gently invert the collection tube 3-5 times and then allow the blood to coagulate for 30 minutes.
- Centrifuge at 3000rpm for 5 minutes to obtain the plasma supernatant.

**Note:**

- Plasma and serum specimens can be stored at 2°C - 8°C for up to 2 weeks or at -18°C for longer periods.
- Do not thaw and freeze the serum or plasma specimens
- Allow frozen specimens to equilibrate to room temperature before using in test.
- Centrifuge serum and plasma samples if precipitate is detected in the sample. Use the supernatant for testing.

# HIV 1/2 Rapid Test

## Instruction for Use

### SPECIMEN COLLECTION AND STORAGE (continued)

- To collect **whole blood** from fingerstick:
- Wipe the finger to be pricked with the alcohol swab provided.
- Use the lancet provided in the following manner:
- Twist the lancet cap more the 180 degrees and remove the cap.
- Place the end face of the lancet on the selected finger site (avoid callus) and apply pressure until you hear a click sound.
- Remove lancet and dispose the used lancet safely in the sharps container
- Wipe away the first drop with absorbent paper or cloth. Gently squeeze the fingertip for a second drop of blood.
- Use the specimen transfer device to collect the specimen. Slight pressure may be applied to the finger to ensure enough blood is available for collection.

### LIMITATIONS

1. **Phila•TEST™ HIV 1/2 Rapid Test** is designed to detect antibodies to HIV-1 and HIV-2 in human serum, plasma and whole blood. Pooled samples or other body fluids may give incorrect test results.
2. **Phila•TEST™ HIV 1/2 Rapid Test** is for qualitative detection of HIV-1 and HIV-2 antibodies in serum, plasma and whole blood. The intensity of the colour of the test line is not an indication of the concentration of antibody in the specimen.
4. A false non-reactive test may occur if the quantity of HIV-1 and HIV-2 antibodies is below the detection limit of the test.
5. A false reactive test may occur due to rheumatoid factors, other viral infections and/or parasitic infections.
6. Anti-coagulants. heparin, EDTA, and citrate do not affect the test result.
7. Serum and plasma samples are best used fresh, but refrigerated and frozen blood samples can be used once thawed to room temperature.
8. Whole blood samples that have good fluidity and are not haemolysed must be used. Frozen whole blood samples are not suitable for use.

### TEST PROCEDURE

1. If the test kit has been stored below 15°C, allow the test device, buffer and specimen to reach room temperature (18-30°C) before testing.
2. Remove the test device from the foil pouch and use within 1h of opening.
3. Label the test device with the patient identification and place on a level, dry and clean surface.

   For **Fingerstick whole blood** specimens, fill the specimen transfer device with whole blood (10$\mu$l). Add the specimen to the sample well (S) of the test device. Allow the blood from the specimen dropper device to drain fully onto the sample pad. Add 4 drops of buffer (approx. 90$\mu$l) to the sample well and start the timer. If the first drop presents as as an air bubble it does not count as a drop.

   For **Serum or Plasma** specimens, hold the dropper vertically and transfer 1 drop of serum or plasma to the sample well (S) of the test device. Add 4 drops of the buffer (approx. 90$\mu$l) to the sample well and start the timer.

   For **Venous whole blood** specimens hold the dropper vertically and transfer 2 drops of whole blood to the sample well (S) of the test device. Add 4 drops of buffer (approx. 90$\mu$l) to the sample well and start the timer.
4. Wait for 15 minutes to read the test. Do not read the test after 20 minutes.

### INTERPRETATION OF RESULTS

**Negative Results:**

The presence of a Control line only indicates that the specimen is non-reactive to HIV-1 and HIV-2.


**Positive Results:**

The presence of two lines indicates HIV infection. One line should always appear at the control line and another one at the test line (T).


**Invalid**

The test is invalid if the control line does not appear. If this occurs, the test should be repeated using a new test kit.



### QUALITY CONTROL

**Phila•TEST™ HIV 1/2 Rapid Test** has a built-in control to confirm the test validity. The appearance of a line in the control test line region "C" indicates that the sample has migrated along the membrane and the test has run correctly.

As per Good Laboratory Practice it is recommended that positive and negative control specimens be used to verify the proper test performance.

### INDEX OF SYMBOLS

| | | | |
|---|---|---|---|
| | CAUTION | 30 °C / 2 °C | Store between 2-30°C |
| | Keep away from sunlight | | Keep dry |
| | Manufacturer | | Do not reuse |
| IVD | For *in vitro* diagnostic use only | Σ N | Contains sufficient for <N> tests |
| REF | Catalogue Number | | Consult instruction for use |
| LOT | Batch Code | | Expiry date |

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