WHO Prequalification of Diagnostics Programme
PUBLIC REPORT
Product: ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device
Number: PQDx 0141-051-00
March 2019, version 07

ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device with product code IHI-T402W\(^1\), manufactured by ABON Biopharm Hangzhou Co., Ltd., rest of world regulatory version, was accepted for the WHO list of prequalified diagnostics and was listed on 25 August 2014.

Report amendments and/or product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

<table>
<thead>
<tr>
<th>Public report amendment</th>
<th>Summary of amendment</th>
<th>Date of report amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version 1 to 5</td>
<td>Addition of one new packaging configuration with code IHI-T402WG and the change of the existing code IHI-T402W to IHI-T0402WA. Another amendment was to address a typographical error.</td>
<td>3 May 2017</td>
</tr>
</tbody>
</table>
| Version 6               | “▪ Supplier of alcohol swab changed its labelling by revising symbol and mailbox  
▪ Physical move of whole blood testing on semi-finished and finished product including product performance evaluation on whole blood specimen to a different location  
▪ Create SET with accessories (and assign Product Code)  
▪ Create a new kit size (and assign Product Code)  
▪ Change the second authorized contact person”. | 1 March 2019             |

Intended use:

HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device is an in vitro diagnostic rapid immunochromatographic assay for the qualitative detection of antibodies to HIV-1, including subtype O, and HIV-2 in venous and capillary whole blood, serum and plasma specimens. The

\(^1\) Product code at time of WHO prequalification was IHI-T402. It was subsequently changed to IHI-T402W and this report amended as indicated in report amendments/product changes table above.
product may be used as an aid in the diagnosis of HIV infection. A reactive result should be confirmed by supplemental testing as part of a validated HIV testing algorithm. This product has not been evaluated on paediatric and neonatal specimens.

**Test principle:**
The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device test strip is pre-coated with HIV-1 and subtype O antigens on T1 test line and HIV-2 antigen on T2 test line. Firstly, specimen and then buffer is added to the specimen well, thus starting the migration of the specimen/buffer. The specimen/buffer passes the conjugate pad which contains a mixture of HIV-1 envelope and capsid antigens and HIV-2 envelope antigen. These detection antigens are conjugated to latex particles. If present, the HIV-1 of HIV-2 antibodies react and bind to the detection antigen-conjugate. The antibody/antigen-conjugate mixture then migrates further and binds to antigens present on the test lines. If the specimen contains antibodies to HIV-1, the specimen will bind to the T1 test line and produce a line, if specimen contains antibodies to HIV-2, the specimen will bind to the T2 test line. As liquid continues to migrate down the test strip, the control line will appear. If the control line is present, in addition to either or both test lines, then the test is reactive for HIV1/2 antibodies. If the specimen does not contain HIV-1 or HIV-2 antibodies, no colored lines will appear for either of the test lines region indicating a non-reactive result. Please note that the appearance of coloured lines at T1 and T2 is highly unlikely to be indicative of co-infection with HIV-1 and HIV-2 but rather is a result of cross-reactivity between antigens. A colored line will appear in the control line region if the migration of liquid has been successful and must be present for the test to be valid. Its presence does not confirm sufficient specimen addition.

If used as a first line (screening) assay, any reactive specimens should be referred for additional testing using another method to confirm reactivity. Depending on the prevalence of disease, this may require one or two additional reactive results on at least two other assays.

**Product test kit contents:**

<table>
<thead>
<tr>
<th>Component</th>
<th>40 tests (product code IHI-T402WA)</th>
<th>40 tests (product code IHI-T402WG)</th>
<th>40 tests (product code IHI-T402WB)</th>
<th>5 tests (product code IHI-T402WC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pouched test devices, with desiccant</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>5</td>
</tr>
<tr>
<td>Sterile safety lancets, single-use</td>
<td>N/A</td>
<td>40</td>
<td>40</td>
<td>N/A</td>
</tr>
<tr>
<td>Capillary tubes, heparinized for 50µl</td>
<td>N/A</td>
<td>40</td>
<td>40</td>
<td>N/A</td>
</tr>
<tr>
<td>Alcohol swabs, 70% ethanol</td>
<td>N/A</td>
<td>40</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Specimen droppers</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>5</td>
</tr>
<tr>
<td>Buffer</td>
<td>2 bottles (3m/vial)</td>
<td>2 bottles (3m/vial)</td>
<td>2 bottles (3m/vial)</td>
<td>1 bottle (3m/vial)</td>
</tr>
<tr>
<td>Instructions for use</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
**Items required but not provided:**

<table>
<thead>
<tr>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Consumables:</strong></td>
</tr>
<tr>
<td>Biosafety waste containers, sharps and non-sharps</td>
</tr>
<tr>
<td>Specimen collection equipment for venous whole blood, if serum/plasma/venipuncture whole blood</td>
</tr>
<tr>
<td><strong>Equipment:</strong></td>
</tr>
<tr>
<td>Timer</td>
</tr>
<tr>
<td>Centrifuge, if serum/plasma</td>
</tr>
</tbody>
</table>

**Storage:**
The test kit should be stored at 2-30 °C.

**Shelf-life upon manufacture:**
24 months

**Warnings/limitations:**

**Warnings**
- For in vitro diagnostic use only.
- Read these instructions carefully before performing the test.
- Apply standard biosafety precautions when handling and disposing of potentially infectious material.
- Handle all specimens as potentially infectious.
- Wear protective clothing such as gloves, laboratory coats, and eye protection when specimens are being tested.
- The test device and accessory should be disposed in a proper biohazard waste container after testing.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Avoid splashes and clean up spills immediately with appropriate disinfectant.
- The buffer contains 0.02% sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with large quantities of water.
- Do not use the test kit beyond the expiration date.
- Do not use if the packaging is damaged.
- Do not use the heparinized capillary tube, dispensing bulb, specimen dropper (for fingerstick whole blood), single-use lancet and alcohol pad if it is already damaged.
- Dispose the heparinized capillary tube, specimen dropper (for fingerstick whole blood), single-use lancet in the sharps container if it is already damaged before use.
- Do not set the lancet down before discarding it.
- Do not use the lancet on more than one person.
- In case of Post-exposure prophylaxis for HIV, operators should familiarize themselves with PEP policy prior to conducting the testing.
- Humidity and temperature can adversely affect results.
- The optimal number of specimens to be tested at one time is ten.

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2 Shelf-life stated at time of original prequalification public report was 24 months.
- Do not use any other specimen than those specified. For plasma/venipuncture whole blood, EDTA-K2/sodium heparin can be used as anticoagulant. Other anticoagulants have not been tested and may give incorrect results.

Limitations

1. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is for *in vitro diagnostic use* only. This test should be used for the detection of antibodies to HIV-1/2 in human whole blood, serum or plasma. The concentration of antibodies to HIV-1/2 cannot be determined by this qualitative test.

2. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to HIV-1/2 in the specimen and should not be used as the sole criteria for the diagnosis of HIV-1, HIV-2, and/or HIV-1 subtype O infection.

3. For confirmation of reactive test results, specimens should undergo further testing using different assays, such as rapid diagnostic tests, EIA and/or Western blotting in accordance with a validated HIV testing algorithm.

4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

5. Results should not be used to determine the genotype of HIV infections.

6. Due to possible antibody cross reactivity, the appearance of lines in both T1 and T2 does not necessarily indicate co-infection from HIV-1 and HIV-2.

7. False reactive results may arise due to rheumatoid factors, antinuclear antibodies, other viral infections (i.e. hepatitis B or hepatitis C), parasitic infections (i.e. schistosomiasis and trypanosomiasis), damage to test components by heat or humidity, when other test kit components (e.g. buffer or droppers) are substituted between test kits.

8. False non-reactive results may arise when titers of antibodies to HIV1/2 are very low, titers of antibodies to HIV1/2 are very high (high-hook effect), insufficient specimen volume added, excess of buffer added, damage to test components by heat or humidity.

9. False-negative results may be observed in individuals who are receiving effective antiretroviral therapy.

### Summary of prequalification status for
**ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Date</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>PQ status amended</td>
<td>27 February 2019</td>
<td>listed</td>
</tr>
<tr>
<td>Status on PQ list</td>
<td>25 August 2014</td>
<td>listed</td>
</tr>
<tr>
<td>Dossier review</td>
<td>14 July 2014</td>
<td>MR</td>
</tr>
<tr>
<td>Site inspection(s) of quality management system</td>
<td>13 August 2014</td>
<td>MR</td>
</tr>
<tr>
<td>Laboratory evaluation of performance and operational characteristics</td>
<td>7 November 2013</td>
<td>MR</td>
</tr>
</tbody>
</table>
ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device was accepted for the WHO list of prequalified diagnostics on the basis of data submitted and publicly available information.

Prioritization for prequalification
Based on the established eligibility criteria, ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device was given priority for WHO prequalification assessment.

Product dossier assessment
ABON Biopharm Hangzhou Co., Ltd. submitted a product dossier for ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device as per the “Instructions for compilation of a product dossier” (PQDx_018 v1). The information submitted in the product dossier was reviewed by WHO staff and external experts (assessors). The manufacturer's responses to the nonconformities found during dossier screening and assessment findings were accepted on 14 July 2014.

Manufacturing site inspection
Two comprehensive inspections were performed at the site of manufacture (Hangzhou, China) of the ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device in September 2012 and in November 2013 as per the “Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics” (PQDx_014 v1). The second inspection found that the manufacturer had an acceptable quality management system and good manufacturing practices in place that ensured the consistent manufacture of a product of good quality. The manufacturer's responses to the nonconformities found at the time of the inspection were accepted on 16 April 2014.

Laboratory evaluation
ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device was evaluated by WHO at the Institute of Tropical Medicine, Antwerp, Belgium - a WHO Collaborating Centre for HIV/AIDS Diagnostics and Laboratory Support. The laboratory evaluation was conducted according to the “WHO protocol for the laboratory evaluation of HIV serology assays” (PQDx_030 v1.0), and drew the following conclusions:

ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device is an immunochromatographic rapid diagnostic test for the discriminatory detection of HIV-1 and HIV-2 antibodies in human serum, plasma, capillary and venous whole blood. A volume of 25µl of serum/plasma or 50µl of whole blood is required to perform the assay. This type of assay requires no sophisticated equipment and can therefore be performed in laboratories with limited facilities and non-laboratory settings. Reading of the results can be done visually.
In this limited evaluation on a panel of 1118 serum/plasma specimens, we observed an initial sensitivity (95% CI) of 100% (99.2% - 100%) and an initial specificity (95% CI) of 99.7% (98.9% - 100%) compared to the reference assays. The final sensitivity (95% CI) was 100% (99.2% - 100%) and the final specificity (95% CI) was 99.7% (98.9% - 100%) compared to the reference assays. In this study, 0% of the results were recorded as indeterminate. Results were interpreted independently by three technicians; the overall inter-reader variability was 3.9% (0.1% for the HIV-1 band, 3.8% for the HIV-2 band). The invalid rate was 0.9%. Lot to lot variation was acceptable for all but one dilution series (WHO3-0690). False reactivity was observed for the HIV-2 test line for the first 4 dilutions when tested with lot HIV 2090089. No false reactivity was observed for the HIV-2 line when the same dilution series was tested with lot HIV 2090023.

ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device was unable to discriminate between HIV-1 and HIV-2 infection for 150 of the 1118 specimens (2 HIV-2 positives and 148 HIV-1 positives). This is a notable limitation of the product.

For eight seroconversion panels, ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device detected on average 0.5 (95% CI -0.3 – 1.0) specimens later than the benchmark assay; Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics). For the mixed titer panel, ABON™ HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device correctly classified all specimens. For the 1st International Reference Panel for anti-HIV [NIBSC code 02/210], ABON™ HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device correctly classified all subtypes tested (HIV-1 A, HIV-1 B, HIV-C, HIV-1 CRF01_AE, HIV-1 O and HIV-2).
Labelling
1. Labels
2. Instructions for use
1. **Labels**

1.1- **BOX**

1.1.1- Test printed on the box

![Box Label](image)

1.1.2- Box labels

IHI-T402WA

![Box Label](image)
IHI-T402WB

HIV 1/2/0 Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)

REF IHI-T402WB
Kit Size: 40 Test devices

Contents:
Test Device x40  Instructions for Use x1  3mL Buffer x2
Single-use Lancet x40  Specimen Dropper for Fingerstick Whole Blood x40
Specimen Dropper for Serum or Plasma or Venipuncture Whole Blood x40

LOT HIV7110074  2019-08
B080502-01

IHI-T402WC

HIV 1/2/0 Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)

REF IHI-T402WC
Kit Size: 5 Test devices

Contents:  Test Device x5  Instructions for Use x1  3mL Buffer x1
Specimen Dropper (For Serum / Plasma / Venipuncture Whole Blood) x5

LOT HIV7110075  2019-08
B080506-01
IHI-T402WG

**HIV 1/2/O Tri-line Human Immunodeficiency Virus**

**Rapid Test Device (Whole Blood/Serum/Plasma)**

**Ref** IHI-T402WG

**Kit Size:** 40 Test devices

**Contents:**
- Test Device x40
- Instructions for Use x1
- 3mL Buffer x2
- Single-use Lancet x40
- Alcohol Swab x40
- Specimen Dropper for Fingerstick Whole Blood x40
- Specimen Dropper for Serum or Plasma or Venipuncture Whole Blood x40

**LOT** HI7060086  2019-05

B080484-01

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1.2 Buffer label

**WB/Serum/Plasma HIV Buffer**

3 mL, for use with WB/Serum/Plasma specimens only

**LOT** HI7060086  2019-05

B080492-01

*Abon Biopharm (Hangzhou) Co., Ltd.*
1.3 Dropper label

1.3.1 Specimen dropper for serum/plasma/venepuncture whole blood

![Specimen dropper for Serum/Plasma/Venipuncture Whole Blood](image1)

1.3.2 Specimen Dropper for Fingerstick Whole Blood

![Specimen dropper for Fingerstick Whole Blood](image2)

1.4 Lancet label

![Lancet label](image3)
1.5 Alcohol swab

Front

Alcohol Prep Pads
Size: Medium
Reorder: 110101001

Antiseptic Isopropyl Alcohol, 70% v/v.
For professional and hospital use.
For external use only.

Made In China
- Non-toxic
- Non-pyrogenic
- Store at room temperature
- Don’t use if package is opened or damaged

Changzhou Maokang Medical Products Co., Ltd
Add: No. 9-P, The North of Dashang Road, Jintan City,
Changzhou, Jiangsu Province, China P.C.: 213220
Tel: +86-519-80105516; Fax: +86-519-80156519
E-mail: tommy.die@maokangmedical.com

Back

**Drug Facts**

**Active ingredient**
Isopropyl Alcohol, 70% v/v.

**Purpose**
Antiseptic

**Use**
For preparation of skin prior to injection.

**Warnings**
For external use only. Flammable, keep away from fire or flame. Do not use with electrocautery procedures ■ in the eyes ■ on mucous membranes ■ on irritated skin. Stop use and ask a doctor if ■ irritation or redness develops. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control center right away.

**Directions**
Wipe injection site vigorously and discard.

**Other Information**
Store at room temperature 15 – 30°C (59 – 86°F)

**Inactive ingredients:** Purified Water
1.6 Pouch

1.3.1- Test printed on the pouch

![Image of the pouch with test printed on it]

1.3.2- pouch ink printing

![Image of the pouch with text printed on it]

HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE(WHOLE BLOOD/SERUM/PLASMA)

<table>
<thead>
<tr>
<th>REF</th>
<th>IHI-T402WP</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>HIV7060086</td>
</tr>
</tbody>
</table>

2019-05
2. Instructions for use
Serum or plasma specimens

4. Draw the specimen from the specimen tube with a dropper.

5. Transfer 1 drop of serum or plasma (approximately 25 μL), then add 1 drop of buffer (approximately 40 μL).

6. Start the timer.

Venipuncture whole blood specimens

4. Draw the specimen from the specimen tube with a dropper.

5. Transfer 2 drops of whole blood (approximately 50 μL), then add 2 drops of buffer (approximately 80 μL).

6. Start the timer.

Fingerstick whole blood specimens

4. Open entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Depress the alcohol swab.

5. Take the cap of the lancet and dispose the cap in sharps container.

6. Rub one-side of the finger. Depress the lancet in sharps container immediately after using.

7. Wipe away the first blood drop with a sterile gauze pad or cotton wool.

8. Immerse the open end of the capillary tube into the blood drop and allow for the blood to draw into the capillary tube up to marked line.

9. After collecting the sample, place a gauze pad on the incision on the finger until the bleeding stops.

10. Place the bulb onto the top edge of the capillary tube.

11. Squeeze the bulb to dispense all whole blood on the specimen well (approximately 30 μL), then add 2 drops of buffer (approximately 50 μL).

12. Dispose the capillary tube in sharps container after testing.

13. Start the timer.

Reagents and Equipment required for testing:
- Specimen tube
- Buffer
- Alcohol swab
- Lancet
- Gauze pad
- Cotton wool
- Capillary tube
- Sharps container

Read results

Wait for the colored band(s) to appear. Read results at 10-20 minutes.

Reactive: Two or three distinct colored lines appear. One line should always appear in the control line region. If two distinct colored lines appear, the sample result is considered positive.

Non-reactive: One colored line appears in the control region. No apparent colored lines appear in the test line region (TT and/or TD).

Invalid: No line appears in the control region. If this occurs, repeat the test procedure again and report the test with a new test device. If the result is still invalid, stop using the test kit immediately and contact your supplier/distributor.

Clearup/Record

Defer devices, gloves in a proper hazardous waste container.

Record the test results.
A rapid diagnostic test for the quantitative detection of antibodies to Pathogen X allows for the simultaneous measurement of antibodies to Pathogen X (IgG and IgA) and Pathogen Y (IgM and IgG) in a single test. This test is based on a lateral flow immunoassay and utilizes a combination of gold nanoparticles and fluorescent beads to detect antibody binding.

**Methodology**

**Materials Required**
- Buffer solution (pH 7.4, 0.05 M)
- Antibody capture beads (conjugated with fluorescent dye)
- Control beads (unconjugated)
- Sample diluent (0.1 M sodium phosphate buffer, pH 7.4)
- Sample (serum, plasma, or cell culture supernatant)
- Spin filter (5 mL)
- Microcentrifuge tubes (15 mL)
- 96-well microplates
- Multichannel pipette
- Centrifuge
- Thermocycler
- Fluorometer

**Protocol**

1. Add 50 μL of sample to each well of the microplate.
2. Incubate for 2 hours at 37°C.
3. Wash the microplate with washing buffer.
4. Add 100 μL of detection reagent to each well.
5. Incubate for 1 hour at 37°C.
6. Wash the microplate again.
7. Add 100 μL of substrate solution to each well.
8. Incubate for 10 minutes at 37°C.
9. Add 50 μL of stop solution to each well.
10. Read the fluorescence at 450 nm using a fluorometer.

**Results**

- Positive results: Fluorescence intensity > cutoff value
- Negative results: Fluorescence intensity ≤ cutoff value

**Interpretation**

- Results are reported as the ratio of sample fluorescence intensity to control fluorescence intensity.
- A value of 1.5 or greater is considered positive.
- A value less than 1.5 is considered negative.

**Quality Control**

- Positive and negative controls are run with each assay.
- The assay is validated using known positive and negative samples.
- The assay is run in duplicate to ensure consistency.

**Conclusion**

This rapid diagnostic test provides a simple and rapid method for detecting antibodies to Pathogen X and Pathogen Y. The test is sensitive, specific, and reproducible, making it suitable for use in clinical settings and public health monitoring.

**References**


**Appendix**

- Table A: Summary of the sensitivity and specificity of the assay.
- Table B: Comparison of the assay with conventional methods.

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**Figures**

- Figure 1: Schematic diagram of the assay setup.
- Figure 2: Fluorescence intensity plot for positive and negative controls.

**Conclusion**

The rapid diagnostic test described above provides a reliable and efficient method for detecting antibodies to Pathogen X and Pathogen Y. Its simplicity, speed, and accuracy make it a valuable tool for clinical and public health applications.
**Materials Provided**

- Device
- Test device
- 3rd culture
- Specimen collector (For Swab/Plaque/Miniature) (White Blood Cells)
- Instructions for use

**Materials Required But Not Provided**

- Specimen collection and equipment
- Cotton swab
- Gelatin (0.5% w/v)
- Time
- Wax
- Temperature
- Urine
- Inoculation

**Procedure**

- Allow the device to buffer and specimen to reach room temperature (15°C–30°C).
- Do not force the device to the floor and push as soon as possible.
- Place the device on a clean and dry surface. Label with specimen ID.
- For skin or plasma samples: Hold the dropper vertically and transfer 5 drops of whole blood aliquots (50–100 μL) to the test well of the test strip (D well) of the test device, add 2 drops of buffer (approximately 40 μL).
- For venipuncture whole blood samples: Hold the dropper vertically and transfer 5 drops of whole blood aliquots (50–100 μL) to the test well of the test strip (D well) of the test device, add 2 drops of buffer (approximately 40 μL).
- For peripheral blood whole blood samples: Hold the dropper vertically and transfer 5 drops of whole blood aliquots (50–100 μL) to the test well of the test strip (D well) of the test device, add 2 drops of buffer (approximately 40 μL).
- For blood collected in EDTA: Hold the dropper vertically and transfer 5 drops of whole blood aliquots (50–100 μL) to the test well of the test strip (D well) of the test device, add 2 drops of buffer (approximately 40 μL).

**Interpretation of Results**

- For skin or plasma samples: After 20 seconds, look at the tip of the test strip, a red bar indicates a positive result.
- For blood samples: After 20 seconds, look at the tip of the test strip, a red bar indicates a positive result.

**Conclusion**

- A correct interpretation of the test results is the main current in the test as an internal control. The test result shall be visually inspected after 20 seconds. The test shall be performed in duplicate, and each test shall be performed in parallel. The test shall be performed at room temperature. The test shall not be performed on devices other than those listed.

**References**

1. MUI/2012 Thromboimmunostaining+ Rapid Test Device (Whole Blood/Serum/Plasma) was evaluated with 1,648 specimens from various locations in Europe, Asia, Africa and Oceania. The indications for the test were skin, plasma and serum specimens. 1,648 were found RRL-Xploratives, 1,648 were found RRL-Xploratives, 1,648 were found RRL-Xploratives, 1,648 were found RRL-Xploratives, 1,648 were found RRL-Xploratives, 1,648 were found RRL-Xploratives, 1,648 were found RRL-Xploratives, 1,648 were found RRL-Xploratives.
**Preparation**

1. **Materials Provided**
   - [Image of materials provided]
   - Materials Required But Not Provided
   - [Image of materials not provided]

2. **Vear gloves**

3. Open the pouch. Label with specimen ID. Use 6 weeks on specimens (within one hour).

**Serum or plasma specimens**

4. Draw the specimen from the specimen tube with a dropper.

5. Transfer 1 drop of serum or plasma (approximately 25 µL), then add 1 drop of buffer (approximately 45 µL).


**Venipuncture whole blood specimens**

4. Draw the specimen from the specimen tube with a dropper.

5. Transfer 2 drops of whole blood (approximately 50 µL), then add 2 drops of buffer (approximately 25 µL).


**Fingerstick whole blood specimens**

4. Open the entire finger tip (preferable 3rd or 4th finger from non-dominant hand) with alcohol wipe. Defer the alcohol wipe.

5. Tear off the cap of the luer lock and dispose the cap in sharps container.

6. Runnenee the side of the finger. Dispose the luer lock in sharps container immediately after using.

7. Wipe away the first blood drop with a sterile gauze pad or cotton wool.

8. Immerse the open end of the capillary tube into the blood drop and allow for the blood to draw into the capillary tube up to marked line.

9. After collecting the sample, place a gauze pad or cotton wad under the finger until the bleeding stops.

10. Near the bulb onto the top end of the capillary tube.

11. Squeeze the bulb to dispense all whole blood on the specimen well (approximately 50 µL), then add 2 drops of buffer (approximately 60 µL).

12. Depress the capillary tube in sharps container after testing.

13. Start the timer.

**Read results**

Wait for the colored bands to appear. Read results at 10-20 minutes.

**REACTIVE:** Two or three distinct colored lines appear. The line should always appear in the control line region (C), and another line or two appear colored lines should appear in the test line region (T1 and/or T2).

**NOTE:** The intensity of the color in the test line region (T1 and/or T2) will vary but any shade of color in the test line region (T1 and/or T2) should be considered reactive.

**NON-REACTIVE:** No colored line appears in the control region (C). No colored line appears in the test line region (T1 and/or T2).

**INVALID:** No line appears in the control line region (C). If this occurs, read the test procedure again and repeat the test with a new test device. If the result is still invalid, store using the test kit immediately and contact the technician.

**Clearup/Record**

Depress device, gloves in a proper biohazard waste container.

Record the test results.