**TruQuick™ HIV P24 40T**

**A rapid qualitative test to detect p24 antigen to HIV 1 in whole blood, serum or plasma.**

** TQ5340  Rx Only**

**INTENDED USE**

TruQuick HIV P24 is a rapid immunoassay for the qualitative detection of p24 antigen to HIV 1 in whole blood, serum or plasma.

**SUMMARY AND EXPLANATION OF THE TEST**

The HIV p24 antigen is a small piece of protein that is found on the capsule of the HIV virus. When a person is infected with HIV, these bits of protein can be found floating in the blood. The HIV p24 antigen rapid test is the test that detects these bits of protein. This test was first developed as a HIV screening test but rapidly ran out of favor due to the development of more advanced NAAT tests.1 The window period for p24 testing is also very small. This test alone is only accurate for between three and six weeks post exposure.2 So it is a test with very limited applications unless combined with HIV p24 antigen test. The presence of p24 antigen in the blood indicated a recent HIV infection.3

TruQuick HIV P24 is a rapid test to qualitatively detect the presence of p24 antigen to HIV 1 in whole blood, serum or plasma specimen. The test utilizes latex conjugate HIV p24 antibody to selectively detect p24 antigen to the HIV type 1 in whole blood, serum or plasma.

**BIOLOGICAL PRINCIPLES**

The membrane is precoated with mouse anti-HIV p24 antibody. During testing, the whole blood, serum or plasma specimen reacts with HIV p24 antibody coated particles in the Test Cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with HIV p24 antibody on the membrane in the test line region. If the specimen contains p24 antigen to HIV type 1, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain p24 antigen to HIV type 1, a colored line will not appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

**REAGENTS/MATERIALS PROVIDED**

***The maximum number of tests obtained from this test kit is listed on the outer box.***

* Test Cassettes: The test contains HIV type 1 p24 coated particles and mouse anti-HIV p24 antibody coated on the membrane.
* Buffer: a buffered solution containing ProClin 300 as a preservation. The Buffer is supplied in a dropper vial ready for use.
* Droppers
* Package insert

**MATERIALS NOT PROVIDED**

* Specimen collection containers
* Centrifuge
* Timer

**PRECAUTIONS**

1. All reagents are for in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or Test Cassettes are handled.
3. Do not use test is pouch is damaged.

4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.

5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

6. The used test should be discarded according to local regulations.

7. Humidity and temperature can adversely affect results.

**HAZARD and PRECAUTIONARY STATEMENTS**

Refer to the SDS, available at [www.meridianbioscience.com](http://www.meridianbioscience.com) for Hazard and Precautionary Statements.

**SHELF LIFE AND STORAGE**

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30 C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

**SPECIMEN COLLECTION AND PREPARATION**

1. TruQuick can be performed using whole blood (from venipuncture or fingerstick) serum or plasma.
2. To collect **Fingerstick Whole Blood specimens**:

* Wash the patient’s hand with soap and warm water or clean with an alcohol swab. Allow to dry.
* Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
* Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
* Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.

Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:

* Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
* Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the Test Cassette.

Add the Fingerstick Whole Blood specimen to the test by using **hanging drops**:

* Position the patient’s finger so that the drop of blood is just above the specimen area of the Test Cassette.
* Allow two hanging drops of fingerstick whole blood to fall into the center of the specimen area on the Test Cassette, or move the patient’s finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.

1. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear nonhemolyzed specimens.
2. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 C for up to three days. For long term storage, specimens should be kept below ‑20 C. Whole blood collected by venipuncture should be stored at 2-8 C if the test is to be run within two days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
4. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

**TEST PROCEDURE**

**Allow the test, specimen, Buffer and/or controls to reach room temperature (15-30 C) prior to testing.**

1. Bring the pouch to room temperature before opening it. Remove the Test Cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.

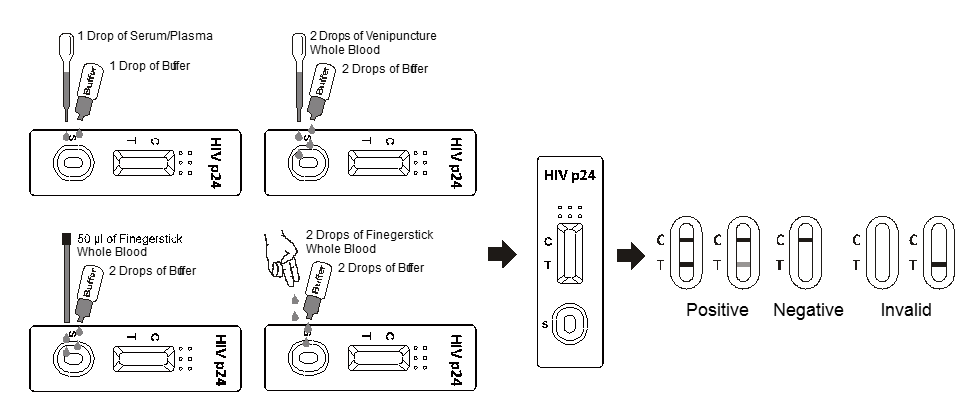
For **Serum or Plasma** specimen: Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 µL) to the specimen area, then **add 1 drop of Buffer** (approximately 40 µL) and start the timer. See illustration below.

For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 µL) to the specimen area, then **add 2 drops of Buffer** (approximately 80 µL) and start the timer. See illustration below.

For **Fingerstick Whole Blood** specimen:

* To use a capillary tube: Fill the capillary tube **and transfer approximately 50 µL of fingerstick whole blood specimen** to the specimen area of Test Cassette, then **add 2 drops of Buffer** (approximately 80 µL) and start the timer. See illustration below.
* To use hanging drops: Allow **2 hanging drops of fingerstick whole blood specimen** (approximately 50 µL) to fall into the specimen area of Test Cassette, then **add 2 drops of Buffer** (approximately 80 µL) and start the timer. See illustration below.

1. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after 20 minutes.



**INTERPRETATION OF RESULTS**

(Please refer to the illustration above.)

**POSITIVE:\* Two lines appear.** One colored line should be in the control line region (C) and another colored line should be in the test line region (T).

**\*NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of HIV p24 antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

**NEGATIVE: One colored line appears in the control line region (C).** No line appears in the test line region (T).

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test Cassette immediately and contact Meridian’s Technical Services Department at 800-343-3858 or your local distributor.

**QUALITY CONTROL**

***This test should be performed per applicable local, state, or federal regulations or accrediting agencies.***

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External Controls are not supplied with this kit; however, it is recommended that positive and negative external controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

**If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian’s Technical Services Department at 1-800-343-3858 (US) or your local distributor.**

**EXPECTED VALUES**

TruQuick HIV P24 was compared with a leading commercial HIV EIA test. The correlation between these two systems is 99.1%.

**LIMITATIONS OF THE PROCEDURE**

1. TruQuick HIV P24 is forin vitro diagnostic use only. The test should be used for the detection of HIV p24 antigen in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in HIV p24 antigen can be determined by this qualitative test.
2. TruQuick HIV P24 will only indicate the presence of p24 antigen to HIV type 1 in the specimen and should not be used as the sole criteria for the diagnosis of HIV infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of HIVinfection.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

**Sensitivity and Specificity**

TruQuick HIV P24 was compared to a leading commercial ELISA HIV test using clinical specimens. The results show that the sensitivity of TruQuick HIV P24 is 96.7% and the specificity is 99.3%.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Method** | | **ELISA** | | **Total Result** |
| TruQuick HIV P24 | Results | Positive | Negative |
| Positive | 29 | 2 | 31 |
| Negative | 1 | 298 | 299 |
| Total Result | | 30 | 300 | 330 |

Sensitivity: 96.7% (95% CI\*: 82.8%~99.9%)\*

Specificity: 99.3% (95% CI\*: 97.6%~99.9%)\*

Correlation: 99.1% (95% CI\*: 97.4%~99.8%) \* \*95% Confidence Intervals

**REPRODUCIBILITY**

**Intra-Assay Precision**

Within-run precision was determined by using 15 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified > 99% of the time.

**Inter-Assay Precision**

Between-run precision was determined by 15 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of TruQuick HIV p24 were tested. The specimens were correctly identified > 99% of the time.

**CROSSREACTIVITY**

TruQuick HIV P24 was tested with specimens from patients diagnosed with HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HCV, Syphilis, HAMA, RF*,* Mononucleosis, CMV, Rubella, Toxoplasma and *H. pylori* positive specimens*.*  There was no crossreactivity with the substances.

**TESTS FOR INTERFERING SUBSTANCES**

The following potentially interfering substances were added to HIV negative and positive specimens.

Acetaminophen 20 mg/dL Caffeine 20 mg/dL

Acetylsalicylic Acid 20 mg/dL Gentisic Acid 20 mg/dL

Ascorbic Acid 20 mg/dL Albumin 2 g/dL

Creatine 200 mg/dL Hemoglobin 1 g/dL

Bilirubin 1 g/dL Oxalic Acid 60 mg/dL

None of the substances interfered in the assay at the concentration tested.

**REFERENCES**

1. Blacklist of English teachers suspected of having AIDS pursued. This image of Randall L Tobias is used in a Korean news article suggesting that foreign English teachers residing in Korea are at risk for AIDS. Accessed 16 Feb 2010.
2. Keeping blood transfusions safe: FDA’s multi-layered protections for donated blood. US FDA Retrieved 12 Oct 2013.
3. FDA approves first nucleic acid test (NAT) systems to screen plasma for human immunodeficiency virus (HIV) and hepatitis C virus (HCV).

**SNTQ5740 REV. 09/17**



**SYMBOL USAGE**

You may see one or more of these symbols on the labeling/packaging of this product:

**Key guide to symbols**

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For technical assistance, call Technical Support Services at 800-343-3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order, call Customer Service Department at 800-543-1980.