InTec PRODUCTS, INC.

REF ITP02009-TC1

Rapid Anti-HIV (1&2) Test

(Whole blood/Serum/Plasma)

FOR IN VITRO DIAGNOSTIC USE ONLY

INTENDED USE

THE ADVANCED QUALITTM RAPID ANTI-HIV(1&2) TEST IS A COLLOIDAL GOLD ENHANCED RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HUMAN IMMUNODEFFICIENCY VIRUS (HIV) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA FROM ALL GROUPS (INCLUDING NEONATES, PREGNANT WOMEN, ETC). THIS TEST IS A SCREENING TEST, AND ALL POSITIVES MUST BE CONFIRMED USING AN ALTERNATE TEST SUCH AS WESTERN BLOT.

SUMMARY AND PRINCIPLE OF THE ASSAY

The human immunodeficiency virus (HIV) is the causative agent of acquired immune deficiency syndrome (AIDS1). The general method of detecting infection with HIV is to observe the presence of antibodies to the virus by an EIA method followed by confirmation with Western Blot2. The Advanced Quality Rapid Anti-HIV (1&2) Test is a simple, visual qualitative test that detects antibodies in human whole blood, serum or plasma. The test is based on immunochromatography and can give a result within 15 minutes.

PRINCIPLE OF THE PROCEDURE

The assay starts with a sample applied to the sample well and add provided sample diluent immediately. The HIV antigen-colloidal gold conjugate embedded in the sample pad reacts with the HIV antibody present in whole blood, serum or plasma sample forming conjugate/HIV antibody complex. As the mixture is allowed to migrate along the test strip, the conjugate/HIV antibody complex is captured by a second antibody immobilized on the membrane forming a colored test band in the test region. A negative sample does not produce a test band due to the absence of conjugate/HIV antibody complex. The antigens used in the conjugate test are recombinant proteins that correspond to highly immunoreactive regions of HIV1 and HIV2. A colored control band in the control region appears at the end of test procedure regardless of test result. The control band indicates that the colloidal gold conjugate is functional.

REAGENTS AND MATERIALS SUPPLIED

- 1 Test card individually foil pouched with a desiccant and a plastic dropper
- 1 Sample diluent
- 1 Safety lancet
- 2 Alcohol swabs
- 1 Instructions for use
- 1 Quick operation guide

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer or stopwatch
2. Biohazard disposal container

STORAGE AND STABILITY

The kit must be stored at 2 – 30°C.

WARNINGS AND PRECAUTIONS

1. All positive results must be confirmed by an alternative method.
2. Treat all specimens as though potentially infectious.
3. Dispose properly after use.
4. Do not use kit materials beyond their expiration dates.
5. Do not interchange reagents from different LOT of kit.
6. Do not re-use the test strips or any single use accessories.

SAMPLE COLLECTION AND STORAGE

Whole Blood

1. The tested whole blood should be drawn with a plastic dropper included in the kit.
2. Gently squeeze and release bulb to collect blood past tip of dropper.
3. Whole blood specimens should be used immediately after collection.

Serum or plasma

1. Collect serum or plasma specimens following regular clinical laboratory procedures.
2. Only those specimens that are clean, clear and with good fluidity can be used for the assay.
3. Those specimens that are apparently hemolyzed, extremely thickened or with very high fat level are NOT suitable for the assay.
4. Storage: A specimen should be refrigerated if not used the same day of collection. Specimens should be frozen if not used within 3 days of collecting. Avoid freezing and thawing the specimens more than 2-3 times before use. 0.1% of sodium azide can be added to specimen as preservative without affecting the results of the assay.

TEST PROCEDURES FOR WHOLE BLOOD

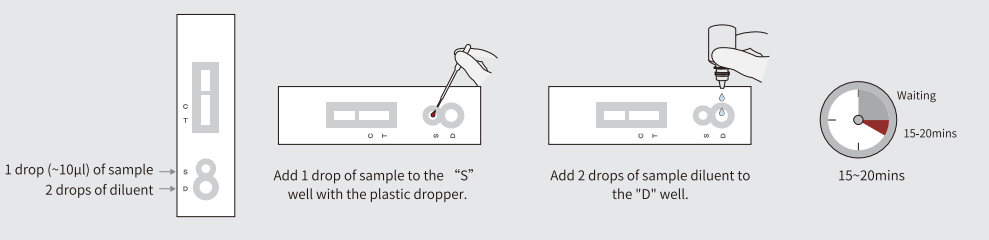
Please read the instructions for use thoroughly before performing the test. Prior to use, the product should be taken out from the storage condition, equilibrated to room temperature, placed on a flat surface.

1. Preparation: Wash your hands and make sure they are dry before starting the test. Clean the finger with alcohol swab and leave it to dry. Place the lancet firmly on side of finger to trigger it.
2. Use dropper to collect blood. Add 1 drop (10μl) of blood to the “S” well with the plastic dropper. Add 2 drops of sample diluent to the “D” well.
3. Wait for 15 minutes to interpret the results. Do not interpret the results after 20 minutes.

TEST PROCEDURE FOR SERUM OR PLASMA COLLECTED BY REGULAR CLINICAL LABORATORY PROCEDURES

Serum or plasma collected following by regular clinical laboratory procedures can also be used for this test.

1. Add 1 drop (10μl) of serum or plasma to the "S" well with the plastic dropper.
2. Then add 2 drops of sample diluent to the "D" well.
3. Wait for 15 minutes to interpret the results. Do not interpret the results after 20 minutes.



READING THE TEST RESULTS

1. Positive:

Both purplish test band and purplish control band appear on the membrane.

2. Negative

Only the purplish control band appears on the membrane. The absence of a test band indicates a negative result.

3. Invalid

There should always be a purplish control band in the control region regardless of test result. If control band is not seen, the test is considered invalid. Repeat the test using a new test card.

Note: ⚠

1. It is normal to have a slightly lightened control band with very strong positive samples as long as it is distinctly visible.
2. Do not interpret the results after 20 minutes.
3. Applying sufficient amount of samples diluents is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop of diluents to "D" well.
4. The positive results could appear as soon as 1 minute for a sample with high level of HIV antibodies.

PERFORMANCE CHARACTERISTICS

1. Specificity

Clinical studies were done to evaluate the performance of Advanced Quality Rapid Anti-HIV (1&2) Test in USA and Canada. In both studies, 119 confirmed negative serum samples (USA: 63 samples and Canada: 56 samples) were tested by Advanced Quality Rapid HIV Test using EIA and Western Blot as reference tests. Both studies gave 100% specificity for the test.

2. Sensitivity

In both the studies mentioned above, Advanced Quality Rapid Anti-HIV (1&2) Test was evaluated with 64 confirmed positive serum samples (32 samples each in USA and Canada). The sensitivity of Advanced Quality Rapid Anti-HIV (1&2) Test was found to be 100% relative to consensus with EIA results, supported by Western Blot assay.

LIMITATIONS

1. Only samples that are clear and with good fluidity can be used in this test.
2. Fresh samples are best but refrigerated and frozen samples can also be used after thawing and balancing to the room temperature. If a sample has been frozen, it should be allowed to thaw in a vertical position
3. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the specimen.

INTERFERING SUBSTANCES

To assess the impact of unrelated medical conditions or interfering substances on the specificity of the ADVANCED QUALITY™ Rapid Anti-HIV (1&2) Test. 207 serum/plasma specimens from a variety of medical conditions unrelated to HIV infection and 114 specimens with interfering substances were analyzed. The results of this study are shown in following Table.

Medical Condition (n=207)	ADVANCED QUALITY™ RAPID Anti-HIV(1&2)POCT RESULTS	
	Reactive	Non-reactive
Multiparous women	0	13
Lupus	0	15
Rheumatoid factor	1	18
Cytomegalovirus(CMV)	0	15
Hepatitis A virus (HAV)	2	18
Hepatitis B virus (HBV)	1	17
Hepatitis C virus (HCV)	0	15
Syphilis	0	15
Toxoplasmosis	0	15
Tuberculosis	0	15
Influenza	0	10
Multiple transfusions	0	10

Medical Condition (n=207)	ADVANCED QUALITY™ RAPID Anti-HIV(1&2)POCT RESULTS	
	Reactive	Non-reactive
Cirrhosis	0	13
Colon cancer	0	11
Chlamydia	0	7
Interfering Substances (n=114)		
Elevated Bilirubin	0	20
Elevated Hemoglobin	0	20
Elevated Triglycerides	0	20
Elevated Protein	0	20
Bacterially Contaminated	0	20
Visual Hemolytic	0	5
Icteric	0	5
Lip emic	0	4

BIBLIOGRAPHY

1. Blattner, W., Gallo, R.C. and Temin. H.M. HIV causes AIDS. Science 241:515, 1988.
2. Curran, J.W., Morgan. W.M., Hardy, A.M., et al. The epidemiology of AIDS: Current status and future prospects. Science 1985, 229:1352:1352-7.

GLOSSARY OF SYMBOLS

	CAUTION		KEEP DRY		DO NOT REUSE		DATE OF MANUFACTURE
	KEEP AWAY FROM SUNLIGHT		TEMPERATURE LIMITATION (2-30°C)		CONSULT INSTRUCTIONS FOR USE		
	MANUFACTURER	IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE		CONTAINS SUFFICIENT FOR ‹N› TESTS		DO NOT USE IF PACKAGE IS DAMAGED
LOT	BATCH CODE	REF	CATALOGUE NUMBER		USE-BY DATE		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