ADVANCED QUALITY™ Rapid Anti-HIV (1&2) Test
(Whole blood / Serum / Plasma)
FOR IN VITRO DIAGNOSTIC USE

INTENDED USE
THE ADVANCED QUALITY™ RAPID ANTI-HIV(1&2) TEST IS A COLLOIDAL GOLD ENHANCED, RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY 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. THE TEST IS INTENDED FOR HEALTHCARE PROFESSIONAL USE ONLY.

SUMMARY
The human immunodeficiency virus (HIV) is the causative agent of acquired immune deficiency syndrome (AIDS). 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 Blot. 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
- Test cards individually foil pouch with a desiccant.
- Plastic dropper
- Sample diluent
- Safety lancet
- Alcohol swab
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED
- Positive and negative controls

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. Wear gloves and protective clothing when handling specimens.
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.

ASSAY PROCEDURES FOR FINGER BLOOD
1. Bring the HIV test card, sample diluent, alcohol swab, safety lancet, plastic dropper.
2. Remove test card from the sealed pouch.
3. To perform the HIV test, please follow the steps closely as following (from picture 1 to picture 8).

1. Clean the finger
2. Bring the safety lancet, and then twist the knob
3. Pull out the knob
4. Place the activated safety lancet firmly on the finger. Push the trigger to prick the finger
READING THE TEST RESULTS

1. Positive

Both purplish test band and purplish control band appear on the membrane. The lower the antibody concentration, the weaker the test band.

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.

Whole blood, serum or plasma collected following by regular clinical Laboratory procedures can also be used for this test.

SAMPLE COLLECTION AND STORAGE

Whole Blood

1. Collect whole blood specimens following regular clinical laboratory procedures.
2. Heparinized capillary tubes must be used for collecting whole blood samples. Do not use hemolyzed blood samples.
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.

BEFORE TESTING

1. Bring the test card, sample diluents and specimens to room temperature.
2. Remove test card from the sealed pouch.

ASSAY PROCEDURE FOR WHOLE BLOOD, SERUM OR PLASMA COLLECTED BY REGULAR CLINICAL LABORATORY PROCEDURES

1. Dispense 1 drop (10ul) of blood, serum or plasma to the “S” well of the test card using the plastic dropper provided according to the figure.
2. Then add two drops of sample diluent to the “D” well.
3. Interpret test results at 15 minutes.
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.

<table>
<thead>
<tr>
<th>Medical Condition (n=207)</th>
<th>ADVANCED QUALITY™ RAPID Anti-HIV (1&amp;2) POCT RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reactive</td>
</tr>
<tr>
<td>Multiparous women</td>
<td>0</td>
</tr>
<tr>
<td>Lupus</td>
<td>0</td>
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<tr>
<td>Rheumatoid factor</td>
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<tr>
<td>Cytomegalovirus(CMV)</td>
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<tr>
<td>Hepatitis A virus (HAV)</td>
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</tr>
<tr>
<td>Hepatitis B virus (HBV)</td>
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</tr>
<tr>
<td>Hepatitis C virus (HCV)</td>
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<tr>
<td>Syphilis</td>
<td>0</td>
</tr>
<tr>
<td>Toxoplasmosis</td>
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</tr>
<tr>
<td>Tuberculosis</td>
<td>0</td>
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<tr>
<td>Influenza</td>
<td>0</td>
</tr>
<tr>
<td>Multiple transfusions</td>
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</tr>
<tr>
<td>Cirrhosis</td>
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</tr>
<tr>
<td>Colon cancer</td>
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<td>Chlamydia</td>
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Interfering Substances ( n=114)

<table>
<thead>
<tr>
<th>Interfering Substances</th>
<th>Reactive</th>
<th>Non-reactive</th>
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</thead>
<tbody>
<tr>
<td>Elevated Bilirubin</td>
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<tr>
<td>Elevated Hemoglobin</td>
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</tr>
<tr>
<td>Elevated Triglycerides</td>
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<td>20</td>
</tr>
<tr>
<td>Elevated Protein</td>
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<tr>
<td>Bacterially Contaminated</td>
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</tr>
<tr>
<td>Visual Hemolytic</td>
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</tr>
<tr>
<td>Icteric</td>
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<td>5</td>
</tr>
<tr>
<td>Lipemic</td>
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</tr>
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BIBLIOGRAPHY
