<table>
<thead>
<tr>
<th>1) What is the name of your company’s HIV testing product or product line?</th>
<th>ValiQuant HIV-1 Quantification Panel</th>
<th>Multispot® HIV-1/HIV-2 Rapid Test</th>
<th>GS HIV-1/-2 Plus O EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>2) What type of test is it (molecular, rapid, etc)?</td>
<td>Molecular</td>
<td>Indirect EIA using recombinant and peptide antigens for detection and differentiation of HIV-1 and HIV-2 antibodies</td>
<td>EIA utilizing recombinant proteins and synthetic peptides for the detection of Ab to HIV-1 (Groups M &amp; O) and/or HIV-2</td>
</tr>
<tr>
<td>3) What is the test’s primary use (blood screening, viral load, genotyping, etc)?</td>
<td>Viral Load Assay Validation</td>
<td>Used as a Rapid EIA to be used as a diagnostic aid for the detection and differentiation of HIV-1 and HIV-2 antibodies.</td>
<td>As an aid in the diagnosis of HIV-1 and/or HIV-2 infection. Also intended for use in the screening of blood donors.</td>
</tr>
<tr>
<td>4) What kind of specimen/sample is tested?</td>
<td>Each panel member contains the entire HIV-1 Genome in an EDTA-based human plasma matrix.</td>
<td>Fresh and/or frozen serum or plasma</td>
<td>Serum, plasma, and cadaveric serum specimens</td>
</tr>
<tr>
<td>5) Where is this product used? Check as many as apply:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• community screening event</td>
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<td>• physician’s office or outpatient clinic</td>
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<tr>
<td></td>
<td>• inpatient’s bedside</td>
<td>• inpatient’s bedside</td>
<td>• inpatient’s bedside</td>
</tr>
<tr>
<td></td>
<td>• inpatient staff-access area</td>
<td>• inpatient staff-access area</td>
<td>• inpatient staff-access area</td>
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<tr>
<td></td>
<td>• critical care unit</td>
<td>• critical care unit</td>
<td>• critical care unit</td>
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<td></td>
<td>• hospital lab</td>
<td>• hospital lab</td>
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<tr>
<td></td>
<td>• other</td>
<td>• other</td>
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</tr>
<tr>
<td>6) If other, please specify:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical laboratories, hospitals, and reference labs</td>
<td></td>
<td>Private and public clinical laboratories, private and public hospitals, reference labs, blood banks</td>
</tr>
<tr>
<td>7) How long does it take to obtain test results, under ideal conditions?</td>
<td>Assay dependent</td>
<td>Results can be obtained in 15 minutes</td>
<td>Results in 2.5 hours</td>
</tr>
<tr>
<td>8) How are test results made available?</td>
<td>Assay dependent</td>
<td>Purple color development (reactive) or no color development (nonreactive) in the three HIV antigen test spots of the membrane. The test also utilizes a test control spot to ensure that the test is performed correctly</td>
<td>Results are reported as reactive or non-reactive. Presence or absence of HIV Ab is determined by relating the absorbance value of the specimen to the cutoff value.</td>
</tr>
<tr>
<td>9) What credentials/licensures are required to run this test?</td>
<td>N/A</td>
<td>The test is CLIA Moderately Complex</td>
<td>The test is CLIA Highly Complex</td>
</tr>
<tr>
<td>10) What is the typical cost?</td>
<td>Contact company</td>
<td>Cost depends on the testing volume</td>
<td>Cost depends on the testing volume</td>
</tr>
<tr>
<td>11) What are the unique benefits to the patient of this test?</td>
<td>Target concentrations are in linear tenfold dilutions spanning a wide dynamic range for easy extrapolation. Little to no preparation necessary for use with new automated HIV assay systems.</td>
<td>The only test in the US to offer detection and differentiation of HIV-1 and HIV-2 antibodies. Two HIV-1 spots, one containing recombinant and the other a synthetic peptide antigen, provides added assurance of an HIV-1 positive result.</td>
<td>It is the only EIA in a microplate format utilizing recombinant proteins and synthetic peptides for the detection of antibodies to HIV-1 (Groups M &amp; O) and/or HIV-2. It is also FDA licensed for use in the screening of blood donors.</td>
</tr>
</tbody>
</table>
### GS HIV-1 Western Blot

- **Test Kit:** 40 test kit
- **Purpose:** Western blot for the detection and identification of antibodies to HIV-1 in human serum, plasma or dried blood spots.
- **Additional Test:** An additional, more specific supplemental test for repeatedly reactive specimens using screening procedures.
- **Usage:**
  - Community screening event
  - Physician’s office or outpatient clinic
  - Inpatient’s bedside
  - Inpatient staff-access area
  - Critical care unit
  - Hospital lab
  - Other
- **Location:** Private and public clinical laboratories, private and public hospitals, reference labs, blood banks
- **Results:** Results can be obtained in 2.5 hours.
- **By Evaluating Each Strip:** By evaluating each strip for the presence of HIV-1 viral bands. A band is defined as a distinct purple line that extends horizontally across the strip where human antibodies have bound to resolved proteins.
- **The Test:** The test is CLIA Highly Complex.
- **Controls:** CAP, CLIA, JCAHO, lab licensure from State
- **Cost:** Cost depends on the testing volume.
- **Quality Control:** Ensures good quality control for accurate patient testing.
- **CLIA:** CLIA waiver

### VIROTROL I Control, VIROTROL HIV-2, AmpliTrol III, VIROCLEAR

- **Purpose:** Third-party controls for HIV testing, EIA/molecular
- **Usage:**
  - Community screening event
  - Physician’s office or outpatient clinic
  - Inpatient’s bedside
  - Inpatient staff-access area
  - Critical care unit
  - Hospital lab
  - Other
- **Location:** Clinical laboratories, blood banks, reference labs
- **Results:** Controls are reported in the same units as patient samples.
- **By Evaluating Each Strip:** The tests are sold to accredited laboratories.
- **The Test:** The laboratory performing the test must be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), and the test must be performed by certified medical technologists.
- **CLIA:** CLIA-waiver

### APTIMA® HIV-1 RNA Qualitative Kit

- **Purpose:** Molecular
- **Usage:** Fingerstick and venipuncture whole blood, serum, or plasma
- **Location:** CLIA-certified lab environment by certified technicians
- **Results:** Depending on logistical conditions, test results can be available within 5 hours of the sample arriving in the laboratory.
- **By Evaluating Each Strip:** Two pink/purple lines, in both the control area and test area, indicate a reactive result (HIV-1 or HIV-2 antibodies are present); while one control line and no test line indicates a nonreactive result.
- **CLIA:** CLIA-waiver

### Clearview COMPLETE HIV 1/2 Rapid test

- **Purpose:** Point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2.
- **Usage:**
  - Community screening event
  - Physician’s office or outpatient clinic
  - Inpatient’s bedside
  - Inpatient staff-access area
  - Critical care unit
  - Hospital lab
  - Other
- **Location:** 15 to 20 minutes
- **The Test:** The only FDA-approved NAAT for acute HIV screening and the first FDA-approved qualitative NAAT that can be used to confirm HIV-1 in a patient who repeatedly tests positive for HIV-1 antibodies.
- **CLIA:** CLIA-waiver

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**Bio-Rad Laboratories**
Maria Rosa Spedaletti
maria-rosa_spedaletti@bio-rad.com
(510) 724-7000
www.bio-rad.com

**Bio-Rad Laboratories**
Richard Russell
richard_russell@bio-rad.com
(949) 598-1200
www.bio-rad.com/qualitycontrol

**Gen-Probe**
Marc Meyers
marcm@gen-probe.com
(800) 523-5001
www.gen-probe.com

**Inverness Medical**
bodytalks@invmed.comusa.com
(877) 546-8633
www.invernessmedicalpd.com

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clpmag.com   |   May  2009   |   23
1. What is the name of your company's HIV testing product or product line?

**Inverness Medical**

bodytalks@invmed.comusa.com  
(877) 546-8633  
www.invernessmedicalpd.com

**OraSure Technologies**

customercare@orasure.com  
(800) ORASURE

www.orasure.com

**PointCare Technologies**

Kim O. Beer  
kbeer@pointcare.net  
(508) 281-6925

www.pointcaretechnologies.com

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2. What type of test is it (molecular, rapid, etc)?

**Cleanview® HIV 1/2 STAT-PAK®**

Rapid test

**OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test**

Rapid point-of-care test

**The PointCare NOW**

Point-of-Care CD4, CD4% and Hematology analyzer

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3. What is the test's primary use (blood screening, viral load, genotyping, etc)?

**Point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2.**

**Screening test for both HIV-1 and HIV-2**

**Monitoring of CD4 T-Cells in HIV/AIDS patients for patient management**

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4. What kind of specimen/sample is tested?

**Fingerstick and venipuncture whole blood, serum, or plasma**

**Oral fluid, fingerstick or venipuncture whole blood or plasma sample**

**Whole blood (2 mL) in a capped vacuum tube**

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5. Where is this product used? Check as many as apply:

- Community screening event
- Physician’s office or outpatient clinic
- Inpatient’s bedside
- Inpatient staff-access area
- Critical care unit
- Hospital lab
- Other

6. If other, please specify:

- Community-based organizations, labor and delivery settings, emergency departments, and accidental exposure situations

- In clinics, HIV/AIDS clinics, decentralized care settings, particularly in low-resource settings

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7. How long does it take to obtain test results, under ideal conditions?

15 to 20 minutes

20 minutes

Seven minutes from blood draw to printed result. There is no sample preparation, manual steps, or incubation. Test is run by a nurse or phlebotomist.

---

8. How are test results made available?

Two pink/purple lines, in both the control area and test area, indicate a reactive result (HIV-1 or HIV-2 antibodies are present); while one control line and no test line indicates a nonreactive result

The test device provides the actual results. The test administrator then delivers the results verbally to the patient.

Results are displayed on display and on printout. 8,000 results are stored onboard for easy download and data management. Results may be provided to clinician and patient immediately.

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9. What credentials/licensures are required to run this test?

CLIA-waiver

No special credentials are required. The test, which is CLIA waived, can be administered by anyone who has undergone the proper training on the product.

Tests are normally run by a nurse or phlebotomist, but any nonspecialized health care provider can run the tests with minimal training.

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10. What is the typical cost?

$17.50/test

$13 to $18

$10 per test shipped from the US. Customs, freight, etc varies by location.

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11. What are the unique benefits to the patient of this test?

Cleanview HIV 1/2 STAT-PAK is a simple cassette based format which utilizes a 5-µL sample for analysis. Sample buffer and 5-µL collection loops are provided with each kit. The test is 99.7% sensitive and 99.9% specific.

The OraQuick ADVANCE Rapid HIV-1/2 Antibody Test is the only FDA-approved rapid HIV test that can be used with oral fluid or blood. The test is CLIA waived and provides results in just 20 minutes.

Tests can be provided at the point of care in any health care facility. Results are provided in minutes—the patient obtains results and can receive consultation in one single visit.
<table>
<thead>
<tr>
<th><strong>RNA Medical</strong></th>
<th><strong>Roche Diagnostics</strong></th>
<th><strong>Trinity Biotech</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patricia Gowdy</td>
<td>Mark Repko</td>
<td>Marlene Jinks</td>
</tr>
<tr>
<td><a href="mailto:pgowdy@RNAMedical.com">pgowdy@RNAMedical.com</a></td>
<td><a href="mailto:mark.repko@roche.com">mark.repko@roche.com</a></td>
<td><a href="mailto:marlene.jinks@trinityusa.com">marlene.jinks@trinityusa.com</a></td>
</tr>
<tr>
<td>(800) 533-6162</td>
<td>(317) 521-2000</td>
<td>(800) 325-3424</td>
</tr>
</tbody>
</table>

**Xera-RHIVXS2-Rapid HIV ½ Antibody Controls** for monitoring the performance of rapid HIV test kits

**Antibody Controls** for monitoring the performance of rapid HIV test kits

**For monitoring the performance of most FDA-cleared rapid HIV-1/2 test kits**

**N/A**

**Human plasma**

**CLIA waived for whole blood, fingerstick, and venipuncture samples; moderate complexity for serum and plasma samples**

**Reference lab**

**5.5 hours for one rack containing up to 21 patient samples**

**In a manner consistent with a CLIA-waived testing.**

**Test results are automatically sent to the AMPLILINK datastation, where they are displayed on a computer screen and stored in a database. The datastation can also be connected to the LIS.**

**On the rapid test kit manufacturer’s instructions.**

**Must participate in the FDA-approved certification program (via Invitrogen)**

**Contact company**

**CLIA accreditation, CAP proficiency testing, relevant state/city/local requirements**

**Contact company**

**Monitor the effects of antiretroviral therapy by measuring changes in EDTA plasma HIV-1 RNA levels during the course of antiretroviral treatment.**

**Uni-gold is the only CLIA-waived rapid HIV screening test in a third-generation format providing 100% sensitivity. Uni-Gold utilizes a simple three-step procedure with results in as few as 10 minutes.**

**Xera is stable for 60 days at room temperature with a 24-month shelf life from date of manufacture. It is for use on FDA-cleared Rapid HIV Test kits and may be used on multiple kit types.**

**COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test**

**Molecular, Real-time PCR**

**Rapid**

**Viral Load**

**Screening**

**CLIA waiver or Moderate Complexity licenses**

**Contact company**

**Roche Diagnostics**

**Trinity Biotech**

**RNA Medical**

**Xera is stable for 60 days at room temperature with a 24-month shelf life from date of manufacture. It is for use on FDA-cleared Rapid HIV Test kits and may be used on multiple kit types.**

**Xera-RHIVXS2-Rapid HIV ½ Antibody Controls for monitoring the performance of rapid HIV test kits**

**Antibody Controls for monitoring the performance of rapid HIV test kits**

**For monitoring the performance of most FDA-cleared rapid HIV-1/2 test kits**

**N/A**

**Human plasma**

**CLIA waived for whole blood, fingerstick, and venipuncture samples; moderate complexity for serum and plasma samples**

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