HVTN HIV Diagnostics Program

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Carissa Karg, MPH

March 14, 2013

The HVTN is supported through a cooperative agreement with the National Institute of Allergy and Infectious Diseases.
HIV Vaccine Trials Network

- Founded in 1999
- Supported by a cooperative agreement with the Division of AIDS, NIAID, NIH
- Collaborative effort of scientists, communities, governments, private companies and NGOs
- Conduct phase 1-3 clinical trials to evaluate HIV Vaccines
- 29 clinical sites
- 50 phase 1-2b clinical trials completed or in progress to date
- 14 additional observational or follow up studies
HVTN Clinical Sites

- U.S.
  - Atlanta
  - Birmingham
  - Boston (2)
  - Chicago
  - Nashville
  - New York (2)
  - Rochester
  - Philadelphia
  - San Francisco
  - Seattle

- HVTN 505 sites
  - Annandale
  - Bethesda
  - Cleveland
  - Dallas
  - Denver
  - Houston
  - Los Angeles
  - New York (Midtown)
  - Orlando

- Switzerland
  - Lausanne

- Haiti
  - Port au Prince

- Peru
  - Lima
  - Iquitos

- Brazil
  - Sao Paulo

- Africa
  - Soweto
  - Klerksdorp
  - Cape Town
Overview of HVTN HIV Diagnostics Program

- In-Study Testing
  - Kit selection
  - Algorithm design
- Endpoint Adjudication
- Evaluation of Seroreactivity (End of study testing)
  - Kit selection
  - Counseling, messaging
- HVTN 910 (VISP Protocol)
- Post Study Testing
- VISP Registry
The HVTN and DAIDS anticipated that VISP will result among study participants and require ongoing testing with an algorithm that distinguishes vaccine induced responses from natural infection.
In-Study Diagnostic Testing

- Only conducted in specialized central laboratories

- Routine Algorithm
  - EIA
  - WB
  - RNA PCR

- Recent Exposure Algorithm
  - EIA, WB and RNA PCR run concurrently (flattened)

- Redraw Algorithm
  - Confirmatory testing from a second blood draw is required to report “infected”

- Reported to clinical site as “infected”, “not infected” or “redraw requested”
Endpoint Adjudication (efficacy studies only)

- In efficacy studies HIV diagnostics identify the endpoints of the study
- Central lab identifies a likely infection
- Results are posted to the adjudication web site
- Adjudicator and designated back up receive email notification
- Web-based tools allow adjudicator to view all diagnostic results and provide a determination within 24 hrs
- Adjudicator posts determination on the website
Adjudication Review

<table>
<thead>
<tr>
<th>Adjudication ID:</th>
<th>PTID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant ID:</td>
<td>PTID</td>
</tr>
<tr>
<td>Status:</td>
<td>Complete</td>
</tr>
<tr>
<td>Case Creation Date:</td>
<td>10AUG2012</td>
</tr>
<tr>
<td>Case Completion Date:</td>
<td>10AUG2012</td>
</tr>
<tr>
<td>Case Comments:</td>
<td>Results indicate infection with HIV-1. [Edit Comments]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EIA Results:</th>
<th>Reactive</th>
<th>Collection Date:</th>
<th>30JUL2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kit:</td>
<td>Biorad Genetic Systems HIV 1/2 Plus O</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Western Blot Results:</th>
<th>Indeterminate</th>
<th>Collection Date:</th>
<th>30JUL2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>WB Bands:</td>
<td>GP160</td>
<td>GP120</td>
<td>P65</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RNA PCR Results:</th>
<th>Detected above limit of quantitation (&gt;10000000 cp/mL)</th>
<th>Collection Date:</th>
<th>30JUL2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kit:</td>
<td>Abbott m2000 Realtime PCR HIV-1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DNA PCR Results:</th>
<th></th>
<th>Collection Date:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Kit:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
EIA Results: Reactive
Kit: Biorad Genetic Systems HIV 1/2 Plus O
Collection Date: 06AUG2012

Western Blot Results: Positive
WB Bands:
<table>
<thead>
<tr>
<th>GP160</th>
<th>GP120</th>
<th>P65</th>
<th>P55</th>
<th>P51</th>
<th>GP41</th>
<th>P40</th>
<th>P31</th>
<th>P24</th>
<th>P18</th>
<th>OTHER_BANDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>++</td>
<td>+/ +</td>
<td>-</td>
<td>+/ -</td>
<td>+/ -</td>
<td>+</td>
<td>++</td>
<td>+/ -</td>
<td>-</td>
<td>-</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Kit: BioRad Genetic Systems HIV-1
Image File: VTN505__PTID__06Aug2012.jpg
Collection Date: 06AUG2012

RNA PCR Results: HIV-1 RNA Detected (4535676 cp/ml)
Kit: Abbott m2000 Realtime PCR HIV-1
Comments: diluted: 300uL sample + 500uL BaseMatrix
Collection Date: 06AUG2012

DNA PCR Results: 
Kit: 

### Adjudication Determination

<table>
<thead>
<tr>
<th>Determination:</th>
<th>completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completion Date:</td>
<td>10AUG2012</td>
</tr>
<tr>
<td>Confirms Infection:</td>
<td>Yes</td>
</tr>
<tr>
<td>Date of Diagnosis:</td>
<td>30JUL2012</td>
</tr>
<tr>
<td>Comment:</td>
<td></td>
</tr>
<tr>
<td>Determ. Completed By:</td>
<td></td>
</tr>
<tr>
<td>Lab Verification of Data Received:</td>
<td>10AUG2012</td>
</tr>
</tbody>
</table>
### HIV-1 Western Blot Worksheet

**Performed by / Date:** 08Aug2012  
**Verified by / Date:** 5th 8/19/12

<table>
<thead>
<tr>
<th>KIT TESTING INFORMATION</th>
<th>CONJUGATE</th>
<th>SAMPLE DILUFENT</th>
<th>TIMER</th>
<th>VTN Run #</th>
</tr>
</thead>
<tbody>
<tr>
<td>KIT MASTER LOTT NO</td>
<td>111315</td>
<td>111324</td>
<td>114352</td>
<td>113772</td>
</tr>
<tr>
<td>KIT EXPIRY</td>
<td>13-Mar-13</td>
<td>111324</td>
<td></td>
<td></td>
</tr>
<tr>
<td>STRIP LOT NO</td>
<td>111324</td>
<td>111324</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NEGATIVE CONTROL</td>
<td>111324</td>
<td>111324</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW POS CONTROL</td>
<td>114245</td>
<td>114245</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIGH POS CONTROL</td>
<td>114245</td>
<td>114245</td>
<td></td>
<td></td>
</tr>
<tr>
<td>COLOR DEVELOPER</td>
<td>114245</td>
<td>114245</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

S/CO < 1.00 = Nonreactive  
**Band Score:** (intensity compared to gp120 on L Pos: (--) = Absent; (+-) = WH; (+) = Same as gp 120; (++) > gp 120 on HPOS

<table>
<thead>
<tr>
<th>#</th>
<th>Aco #</th>
<th>S/CO</th>
<th>Patient ID</th>
<th>Blots</th>
<th>gp 160</th>
<th>gp 120</th>
<th>p65</th>
<th>p55</th>
<th>p51</th>
<th>gp41</th>
<th>p40</th>
<th>p31</th>
<th>p24</th>
<th>p18</th>
<th>other</th>
<th>RESULT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>112530</td>
<td>213</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>112530</td>
<td>213</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>112530</td>
<td>215</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note:** Document presence or absence of "Other" for INDET blots

**worksheet updated 03Aug2011**

**PTID**
Evaluation of Seroreactivity (EOS)

- a.k.a. End of Study testing
- Conducted on all vaccine recipients in all HVTN studies
- Includes at least 3 different serological kits selected for the region
- Attempts to assess the risk of a participant having a reactive test if they are released for outside testing
- Does not provide information on durability of VISP beyond this time point (usually 6 months post last vaccination)
- Reactivity can vary dramatically by testing kit
- Reactivity can vary dramatically by treatment group
### HVTN 204 Evaluation of Seroreactivity

**VRC DNA/Ad5 - EnvABC, Gag, Pol (Nef)**

<table>
<thead>
<tr>
<th>Assay Type</th>
<th>Kit Name</th>
<th>Reactivity</th>
<th>Rate</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any</td>
<td>Any</td>
<td>203/232</td>
<td><strong>87.50%</strong></td>
<td>(82.6%, 91.2%)</td>
</tr>
<tr>
<td>ELISA</td>
<td>Abbot HIVAB HIV 1/2 (rDNA)</td>
<td>199/232</td>
<td><strong>85.80%</strong></td>
<td>(80.7%, 89.7%)</td>
</tr>
<tr>
<td>ELISA</td>
<td>BioRad Genetic Systems HIV 1/2 Plus O EIA</td>
<td>14/232</td>
<td><strong>6.00%</strong></td>
<td>(3.6%, 9.9%)</td>
</tr>
<tr>
<td>ELISA</td>
<td>Biorad Genetic Systems rLAV</td>
<td>77/147</td>
<td>52.40%</td>
<td>(44.3%, 60.3%)</td>
</tr>
<tr>
<td>ELISA</td>
<td>bioMerieux Vironostika HIV-1</td>
<td>43/85</td>
<td>50.60%</td>
<td>(40.2%, 61.0%)</td>
</tr>
<tr>
<td>Western Blot</td>
<td>BioRad Genetic Systems HIV-1</td>
<td>136/204</td>
<td>66.70%</td>
<td>(59.9%, 72.8%)</td>
</tr>
</tbody>
</table>
**HVTN 091 (IAVI B003) EOS Ad26EnvA / Ad35EnvA**

<table>
<thead>
<tr>
<th>Assay Type Kit Name</th>
<th>Reactivity</th>
<th>Rate</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any</td>
<td>62/63</td>
<td>98.40%</td>
<td>(91.5% - 99.7%)</td>
</tr>
<tr>
<td>ELISA Abbott Axsym HIV Ag/Ab Combo</td>
<td>42/47</td>
<td>89.40%</td>
<td>(77.4% - 95.4%)</td>
</tr>
<tr>
<td>ELISA Biorad GenScreen Ultra HIV Ag-Ab HIV ½</td>
<td>29/63</td>
<td>46.00%</td>
<td>(34.3% - 58.2%)</td>
</tr>
<tr>
<td>ELISA Biorad Multispot HIV-1/HIV-2 Rapid Test</td>
<td>2/16</td>
<td>12.50%</td>
<td>(3.5% - 36.0%)</td>
</tr>
<tr>
<td>ELISA bioMerieus Vironostika HIV Ag/Ab HIV ½</td>
<td>61/63</td>
<td>96.80%</td>
<td>(89.1% - 99.1%)</td>
</tr>
</tbody>
</table>
VISP can vary by treatment group

Example: HVTN 078

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Assay Type</th>
<th>Reactivity</th>
<th>Rate</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/N/Ad510^{10}</td>
<td>Any</td>
<td>12/29</td>
<td>41.40%</td>
<td>(25.5%, 59.3%)</td>
</tr>
<tr>
<td>Ad510^8/N/N</td>
<td>Any</td>
<td>2/15</td>
<td>13.30%</td>
<td>(3.7%, 37.9%)</td>
</tr>
<tr>
<td>Ad5 10^9 /N/N</td>
<td>Any</td>
<td>1/15</td>
<td>6.70%</td>
<td>(1.2%, 29.8%)</td>
</tr>
<tr>
<td>Ad5 10^{10} /N/N</td>
<td>Any</td>
<td>10/15</td>
<td>66.70%</td>
<td>(41.7%, 84.8%)</td>
</tr>
</tbody>
</table>
Evaluation of Seroreactivity (EOS) Policy

- Current policy
  - All vaccinees that are positive on any kit at EOS are urged to continue to be tested by the HVTN.
  - If a vaccinee is negative on all kits they are “released” for testing in the community, but counseled that their VISP status can change depending on kit development and their own immune system.
Potential New Policy(?)

- If more than ___% of vaccinees are positive on any kit at EOS, then all vaccinees are urged to test with the HVTN until they have tested negative 3 times over a period greater than 1 year.

- If less than ___% of vaccinees are positive, then only those that are positive are urged to continue to test with the HVTN (the rest are offered that option if they so desire?).

- All are “released” for testing in the community once they have tested negative 3 times over a period greater than 1 year.
Expected to produce 1125 VISP participants based on phase 2a data (~90% of vaccinees)

These are high risk participants who will likely require testing more frequently than phase 1-2a participants

We need to prepare, and budget, for a potentially significant increase in post-study testing as 505 participants come off study.

How long will we need to test these participants?
HVTN 910 (VISP Protocol)

- Allows collection and analysis of post-study HIV diagnostic testing data
- Enrollment of any former HVTN trial participants who exhibited VISP at the end of their parent study (may expand this to non-VISP ppts)
- Allows for storage of additional specimen collected when participants come in for testing
- No set visit schedule, low risk participants encouraged to come in every 6 months. High risk participants test as necessary/desired
- Will eventually provide data on durability of VISP across multiple regimens and multiple serologic kits
- Currently 322 participants enrolled from 24 protocols
- 50 protocols are eligible
- 21 sites are activated
910 report fields

- 910 PTID
- Testing data protocol (910 or parent protocol EOS)
- Parent protocol
- HIV vaccines administered
- Schedule of administration (ex. 0, 1, 2, 6)
- Regimen (ex. DDMM, MMM, DDDAd5, etc)
- Parent treatment group (Ex T1, T2)
- Last vaccination date
- Draw date
- Time since last vaccination (months)
- Number of vaccinations received
- Test kit results, currently 12 kits and WB
# HVTN 204 EOS and post study reactivity from HVTN 910

<table>
<thead>
<tr>
<th>Kit</th>
<th>6 months post last vac</th>
<th>rate</th>
<th>5 -7 years post last vac</th>
<th>rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioRad genetic systems HIV 1/2 plus O</td>
<td>14/232</td>
<td>6.0%</td>
<td>0/16</td>
<td>0%</td>
</tr>
<tr>
<td>BioRad Genscreen HIV 1/2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BioRad Multispot HIV-1/HIV-2 rapid test</td>
<td></td>
<td></td>
<td>3/16</td>
<td>18.8%</td>
</tr>
<tr>
<td>BioRad Genetic Systems rLAV</td>
<td>77/147</td>
<td>52.4%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BioRad Genscreen Ultra HIV Ag-Ab HIV 1/2</td>
<td></td>
<td></td>
<td>0/12</td>
<td>0%</td>
</tr>
<tr>
<td>BioMieurex Vironostika</td>
<td>43/85</td>
<td>50.6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BioMerieux xVironostika Uniform II plus O</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BioMerieux Vironostika HIV Ag/Ab</td>
<td></td>
<td></td>
<td>12/13</td>
<td>92.3%</td>
</tr>
<tr>
<td>AbbottMurex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abbott HIV AB HIV1_2 rDNA</td>
<td>199/232</td>
<td>85.8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abbott Axsym Ag/Ab Combo</td>
<td></td>
<td></td>
<td>11/13</td>
<td>84.6%</td>
</tr>
<tr>
<td>Abbott Architect HIV Ag/Ab Combo</td>
<td></td>
<td></td>
<td>5/15 reactive, 4/15 ind.</td>
<td>33.3%</td>
</tr>
</tbody>
</table>
Overall cost depends on the VISP rate in the primary serologic assay at each time point
- Every positive EIA triggers a WB and viral load

Attempt to make an educated guess on VISP rate for primary EIA based on vaccine inserts and similar product types, for example:
- Minimal Ab induced by DNA vaccines
- Some Ab induced by viral vectors
- Potent Ab induced by recombinant protein / adjuvants
- Env containing products have higher VISP rate

Alternate kit may need to be selected for primary serologic assay in algorithm
- Example: Step Study switched from Unigold to Multispot due to higher level of VISP detection in Unigold
When does the cost of the algorithm exceed the cost of running RNA PCR on all participants In-Study

<table>
<thead>
<tr>
<th>Lab</th>
<th>EIA</th>
<th>Western Blot</th>
<th>Viral Load</th>
<th>Total Algorithm if all 3 tests are run</th>
<th>In-Study Break-Even VISP rate to run VL assay only</th>
</tr>
</thead>
<tbody>
<tr>
<td>UW</td>
<td>$10</td>
<td>$24</td>
<td>$56</td>
<td>$90</td>
<td>~62%</td>
</tr>
<tr>
<td>NICD</td>
<td>$5</td>
<td>$41</td>
<td>$49</td>
<td>$95</td>
<td>~52%</td>
</tr>
<tr>
<td>Lab A</td>
<td>$10</td>
<td>$30</td>
<td>$40</td>
<td>$80</td>
<td>~50%</td>
</tr>
<tr>
<td>Lab B</td>
<td>$10</td>
<td>$30</td>
<td>$25</td>
<td>$65</td>
<td>~38%</td>
</tr>
<tr>
<td>Lab C</td>
<td>$10</td>
<td>$30</td>
<td>$15</td>
<td>$55</td>
<td>~27%</td>
</tr>
</tbody>
</table>
The availability of a reliable, FDA approved serological kit that is insensitive to vaccine induced responses would greatly reduce the frequency of running the entire algorithm for certain vaccine products. It would not eliminate the need for the algorithm.

The availability of a high throughput, inexpensive, FDA approved nucleic acid test would eliminate the need for an algorithm during In-Study testing.

- Would not necessarily be used as point of care
- Would not solve post-study testing issues as long as serologic kits are the standard of care.
Post Study Testing and VISP Registry
Carissa Karg, MPH

- Post Study Testing at the CRS
- HVTN VISP Testing Service
  - Implementation
  - Management
- VISP Registry
- Projected workload
- Next steps
HVTN Post-study Testing Options

<table>
<thead>
<tr>
<th>Off-site</th>
<th>HVTN CRS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EOS testing at End of Study</td>
</tr>
<tr>
<td></td>
<td>VISP?</td>
</tr>
<tr>
<td>YES</td>
<td>HVTN VISP Testing Service</td>
</tr>
<tr>
<td></td>
<td>HVTN 910</td>
</tr>
<tr>
<td>NO</td>
<td>Visit 99.9 (post-study testing)</td>
</tr>
<tr>
<td></td>
<td>Community testing*</td>
</tr>
</tbody>
</table>

*Community testing acceptable with caveat that VISP could appear if vaccine product received during study
Post Study Testing at the CRS

- No cost for study participants
- Testing available upon request
- HVTN diagnostic algorithm used to determine VISP vs. true HIV infection
- Specimens shipped to HVTN diagnostic labs (UW-VSL or NICD) for processing/analysis
- Data systems in place to log and report results directly to CRS
Free post-study HIV testing for participants who no longer have access to their CRS
  - CRS is closed OR
  - participant has moved away from CRS

Intended for participants who have received an investigational HIV vaccine product in DAIDS-funded HIV preventive vaccine trial

Opened August 2010 for U.S. participants
  - Southern Africa expansion discussions underway
HVTN VISP Testing Service, continued

- VISP Testing Service provides:
  - Free HIV testing via a toll free 800 number
    - Local contract phlebotomy service provider(s)
    - Centralized diagnostic labs for analysis
  - Mitigation of social harms
    - e.g. provision of letters to health care and insurance providers verifying VISP status
  - Pre and post-test counseling
  - Resources and referrals
63 participants have used this service to date
- Basic testing - 63%
- Blood donation - 14%
- Pregnancy - 13%
- Insurance policies - 7%
- Military - 3%

Anticipate an increase in testing requests (HVTN 505)
Implementation of the VISP Testing Service

- Key elements:
  - Create stakeholders working group
  - Develop administrative process and documents
  - Identify methods for access (e.g. designated phone, 800 number)
  - Create informational materials for sites, participants, healthcare providers
  - Train staff
  - Identify mechanism to verify study participation
Challenges:
- Identifying local/mobile phlebotomy services
- Testing outside of US
- State counseling, testing and reporting requirements
- Identifying mechanism to confirm study participation
  - Registry/database of participants

Communications
- CRS staff
- Participants
- Health care providers
Management of the VISP Testing Service

- Oversight:
  - Dedicated project manager
  - VISP Counselor(s)
    - Primary
    - Back-ups
  - Additional representatives from stakeholders working group:
    - ethical/legal
    - lab
    - community education
    - clinical trials operations
    - data management
    - medical monitor
Management, continued

- **Challenges:**
  - **Personnel time**
    - No FTEs assigned to program
    - Approx. 3 hours/participant
  - **Cost per participant**
    - $105-$140 kit, shipping, phlebotomy
    - $96 VISP Counselor counseling & administrative tasks
    - $120-$180 lab labor costs
    - $114-$118 VISP algorithm testing (3 EIAs, WB, PCR)
  - **Total per participant** = $435-$534
  - **Growing workload**
  - **Unique cases** (e.g. pregnancy, military, blood donation, false diagnosis)
  - **Verification of study participation**
  - **Obtaining records from closed sites**
VISP Registry

☐ Purpose:

- To verify previous study participation and receipt of HIV vaccine product quickly to facilitate further HIV testing

☐ Implementation:

- Following enrollment, participant names are added to the VISP Registry as participants consent to have their names associated with data already listed in the VISP Registry
VISP Registry Data

- Auto-generated information in VISP Registry:
  - Participant ID
  - Network
  - Protocol number
  - Original site
  - Enrollment
  - Date
  - Date of birth/age at enrollment
  - Estimated current age
  - Gender
  - “VISP potential” = anyone who received an HIV vaccine in a treatment group
  - No HIV test results
Entering Participants in the VISP Registry

- Populating the registry via consent:
  - At CRS
  - Post enrollment in HIV vaccine study
  - HVTN 910
  - VISP Testing Service
  - Intake

- Steps to enter names:
  1. Consent
  2. Enter name
  3. Confirm
VISP Registry Security

- Housed in Atlas (secure web-based system)
- Limited access
  - Training
  - Password-protected
- Data export not possible
Projected Workload

Prospective HIV vaccine trials through 2016

- US and Switzerland: 1250
  - At risk: 1311
  - Low risk: 260
- Latin and South America: 255
- Southern Africa: 6400
  - At risk: 762
  - Low risk: 260

Geographical regions and HIV vaccine recipients.
VISP Testing Service -- Next Steps:

- Southern Africa expansion
- Identify additional phlebotomy options
- Identify additional resources for anticipated growth in testing requests
- Standardize guidance for release to community testing
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