

# Improved HIV Diagnostic Report Turnaround Time Using the HIV Algorithm Workflow System (HAWS)

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Conflict of interest: None



# University of Washington Retrovirology Laboratory

HIV diagnostic testing laboratory at Harborview Medical Center  
Seattle, Washington

Virology Specialty Laboratory for the AIDS Clinical Trials Group

Diagnostic testing laboratory for the HIV Vaccine Trials Network (HVTN)

~ 500 clinical trial participants are tested per week

~ 30 clinics world wide



# What is the need?

- HIV infection detection
- Vaccine Induced Sero-reactivity/positivity (VISR/VISP)
- Pre Exposure Prophylaxis (PrEP) use among participants
- Compliance with protocol-specific testing algorithms
- Interpretation of algorithm test results in the context of study product
- Individual infection status reports to research sites (blinded and unblinded)
- Data tracking and audit readiness

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- Interpretation of algorithm test results in the context of study product
- Individual infection status reports to research sites (blinded and unblinded)
- Data tracking and audit readiness
  
- Turnaround time (TAT)!

# HIV Algorithm Workflow System (HAWS)

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- Developed for the HIV Vaccine Trials Network (HVTN)
  - Adapted from the Test Tracker system
    - A UW-Statistical Center for HIV/AIDS Research and Prevention (SCHARP) collaboration
  - Vaccine and Antibody Mediated Prevention Studies
  - Four HVTN laboratories around the world

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- Developed for the HIV Vaccine Trials Network (HVTN)
  - Adapted from the Test Tracker system
    - A UW-Statistical Center for HIV/AIDS Research and Prevention (SCHARP) collaboration
  - Vaccine and Antibody Mediated Prevention Studies
  - Four HVTN laboratories around the world
- HAWS provides:
  - Defined HIV diagnostic testing algorithms
  - Data management system
  - Individual infection status reports



# 1. LDMS shipment import and aliquot storage



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## Shipping Manifest

**Batch Number: 116**

**QA/QC Not performed**

**Setup Date:** 06/Feb/2019 **Sorted by:** None

**Shipped:** Yes **Ship Date** 06/Feb/2019

<b>Shipped From:</b>				<b>Shipped To:</b>			
<b>Lab ID:</b>	74			<b>Lab ID:</b>	15		
<b>Lab Name:</b>	UCLA School of Medicine 650 Charles E. Young Drive South Room 22-457 MDCC Los Angeles CA 90095-1752			<b>Lab Name:</b>	RETROVIRUS LABORATORY - CAP# 2463716-08 RESEARCH & TRAINING BUILDING, Room: 725 300 NINTH AVE. SEATTLE WA 98104-2499		
<b>Country:</b>	United States			<b>Country:</b>	UNITED STATES		
<b>Contact:</b>				<b>Contact:</b>			
<b>Phone #:</b>	(310) 825-9161			<b>Phone #:</b>	(206) 897-5210		
<b>Fax #:</b>	(310) 206-4764			<b>Fax #:</b>	(206) 897-5237		
<b>E-mail:</b>				<b>E-mail:</b>	DRAGAVON@U.WASHINGTON.EDU		
<b>Number of Specimens</b> 9							
<b>Comments:</b>							

## Shipping Manifest

**Box Name: \*001**

**Batch Number:** 116

**Setup Date:** 06/Feb/2019

**Shipped:** Yes

**Ship Date** 06/Feb/2019

Spec ID	Global Spec ID	Group/Prot	PID/ID1	VID	Clinic	Spec Date or Harvest Date	Spec Time	Prim	Add	Der	Sub A/D	Volume	Pos
074V19000002	J26006HD-01	VTN 704.0	999400115	1.00 Vst	V109	22/Jan/2019	13:20	BLD	EDT	PL1	N/A	1.00 ML	1, 1
074V19000002	J26006HD-02	VTN 704.0	999400115	1.00 Vst	V109	22/Jan/2019	13:20	BLD	EDT	PL1	N/A	1.00 ML	1, 2
074V19000002	J26006HD-03	VTN 704.0	999400115	1.00 Vst	V109	22/Jan/2019	13:20	BLD	EDT	PL1	N/A	1.00 ML	1, 3
074V19000004	K26006HJ-01	VTN 704.0	999400054	2.00 Vst	V109	30/Jan/2019	09:38	BLD	EDT	PL1	N/A	1.00 ML	1, 4
074V19000004	K26006HJ-02	VTN 704.0	999400054	2.00 Vst	V109	30/Jan/2019	09:38	BLD	EDT	PL1	N/A	1.00 ML	1, 5
074V19000004	K26006HJ-03	VTN 704.0	999400054	2.00 Vst	V109	30/Jan/2019	09:38	BLD	EDT	PL1	N/A	1.00 ML	1, 6
074V19000006	J26006HN-01	VTN 704.0	999400021	1.00 Vst	V109	01/Feb/2019	13:10	BLD	EDT	PL1	N/A	1.00 ML	1, 7
074V19000006	J26006HN-02	VTN 704.0	999400021	1.00 Vst	V109	01/Feb/2019	13:10	BLD	EDT	PL1	N/A	1.00 ML	1, 8
074V19000006	J26006HN-03	VTN 704.0	999400021	1.00 Vst	V109	01/Feb/2019	13:10	BLD	EDT	PL1	N/A	1.00 ML	1, 9

# 1. LDMS shipment import and aliquot storage

	Group	TYPE1	ID1	TYPE2	ID2	TYPE3	ID3	Visit	Unit	OPID	CLINIC	Detail
1	VTN	PID	999400021	PROTOCOL	704.0			11.00	Exp		V109	Details
2												Details
3												Details
4												Details
5												Details
6												Details

Spec. Date: 05/Feb/2019	Exp. Date: 0	<input type="checkbox"/> Remote	VQA
Rec. Date: 06/Feb/2019	Recd Time: 14:59	<input type="checkbox"/> Imported	Culture Derivative
Export ID:		Import date:	Enter Specimen ID

# of Tubes: 0	Primary Type: BLD	Other Spec ID:	Spec. Time: _:_	Add	Delete
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	Specimen #	Global Spec ID	Primary	Additive	Volume	Units	Spec Time	Time	Time Unit	Cond	Other Spec Id	Details
1	015V19000242	K0F15GSQ-00	BLD	EDT	10.00	ML	11:32			SAT		ELDB

# of Aliquots: 0	Vol: 0	Units: ML	Derivative:	Sub Add/Der:	Other Spec ID:	Add	Delete	Modify	Clear
------------------	--------	-----------	-------------	--------------	----------------	-----	--------	--------	-------

	Specimen	Global Spec ID	Primary	Add	Der	Sub Add/Der	Volume	Units	Cond	Other Spec Id	Group/ID	Details
1	015V19000242	K0F15GSQ-01	BLD	EDT	PL1	N/A	1.00	ML	SAT		VTN/704.0	ELRDBN
2	015V19000242	K0F15GSQ-02	BLD	EDT	PL1	N/A	1.00	ML	SAT		VTN/704.0	ELRDBN
3	015V19000242	K0F15GSQ-03	BLD	EDT	PL1	N/A	1.00	ML	SAT		VTN/704.0	ELRDBN

e.g. Group, PID, Protocol, Visit, Visit unit, Clinic, Specimen date, Specimen time, Import/Received date

# 1. LDMS shipment import and aliquot storage

Visit type	LDMS visit code	Aliquot storage	HAWS Auto-orders
Routine	VST	1 PLA → VTN AB 2 PLA → VTN Store	HIV-1/2 Ag/Ab Combo
Recent Exposure/Acute Infection	EXP	1 PLA → VTN AB 1 PLA → VTN RNA 1 PLA → VTN Store	HIV-1/2 Ag/Ab Combo HIV-1 RNA
Evaluation of Sero-reactivity	EOS	1 PLA → VTN AB 2 PLA → VTN Store	HIV-1/2 Ag/Ab Combo (mfr. # 1) HIV-1/2 Ag/Ab Combo (mfr. # 2) HIV-1/2 Ag/Ab Combo (mfr. # 3)

# 1. LDMS shipment import and aliquot storage

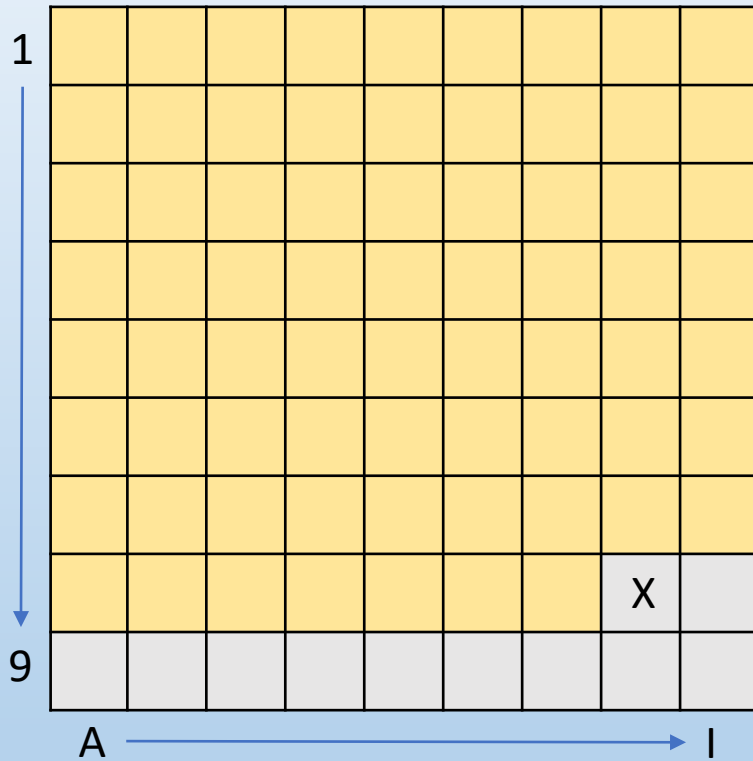
Visit type	LDMS visit code	Aliquot storage	HAWS Auto-orders
Routine	VST	1 PLA → VTN AB 2 PLA → VTN Store	HIV-1/2 Ag/Ab Combo
Recent Exposure/Acute Infection	EXP	1 PLA → VTN AB 1 PLA → VTN RNA 1 PLA → VTN Store	HIV-1/2 Ag/Ab Combo HIV-1 RNA
Evaluation of Sero-reactivity	EOS	1 PLA → VTN AB 2 PLA → VTN Store	HIV-1/2 Ag/Ab Combo (mfr. # 1) HIV-1/2 Ag/Ab Combo (mfr. # 2) HIV-1/2 Ag/Ab Combo (mfr. # 3)

# 1. LDMS shipment import and aliquot storage

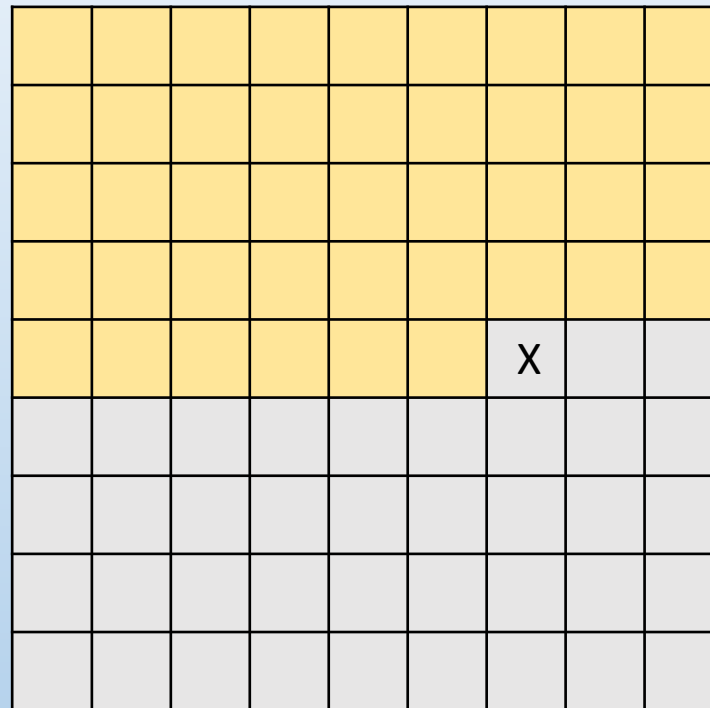
Visit type	LDMS visit code	Aliquot storage	HAWS Auto-orders
Routine	VST	1 PLA → VTN AB 2 PLA → VTN Store	HIV-1/2 Ag/Ab Combo
Recent Exposure/Acute Infection	EXP	1 PLA → VTN AB 1 PLA → VTN RNA 1 PLA → VTN Store	HIV-1/2 Ag/Ab Combo HIV-1 RNA
Evaluation of Sero-reactivity	EOS	1 PLA → VTN AB 2 PLA → VTN Store	HIV-1/2 Ag/Ab Combo (mfr. # 1) HIV-1/2 Ag/Ab Combo (mfr. # 2) HIV-1/2 Ag/Ab Combo (mfr. # 3)

# 1. LDMS shipment import and aliquot storage

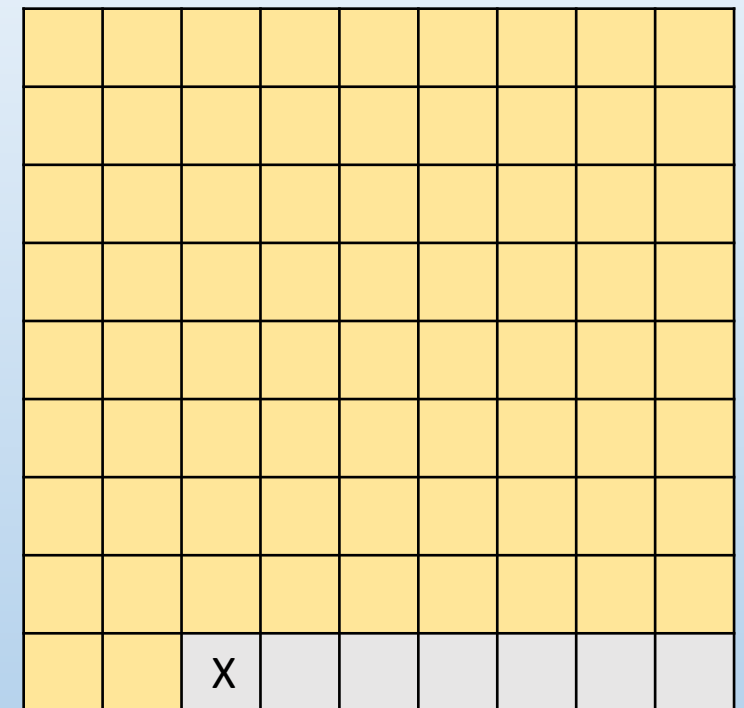
VTN AB Box #1031



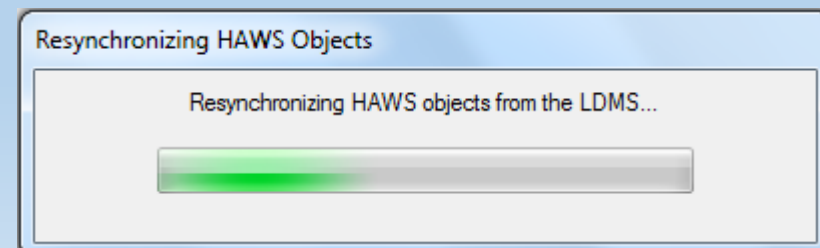
VTN RNA Box #245



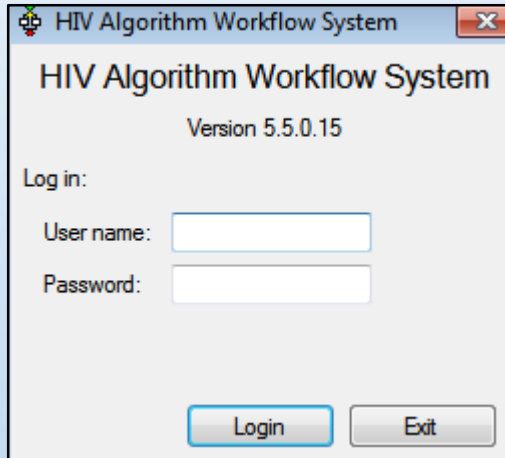
VTN Store Box #962



X = next available spot in the storage box



## 2. Start workflows in HAWS



HAWS  
tracks the  
individual  
performing  
each step

Common Tasks

[Assign a patient visit to a workflow](#)

[All tasks](#)

[Select sample task list](#)

[Process assay task list](#)

[Submit redraw task list](#)

[Receive redraw task list](#)

[Review assay task list](#)

[Result algorithm task list](#)

[Final report task list](#)

[Manage runs](#)

[View all workflows](#)

[Reassign specimen for a test](#)

Group: VTN - HIV

**Optional search filters**

Patient ID:

Study:

Visit unit:

Search

Select one or more patients

Patient ID	Study
999400021	704
999400054	704
999400115	704

Start workflow

02/06/2019 16:14:23: Logged in as E. Goecker (EG)



## 2. Start workflows in HAWS

HIV Algorithm Workflow System

File View Reports Tools Help

### Common Tasks

[Assign a patient visit to a workflow](#)

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Group: VTN - HIV Vaccine Trials

**Optional search filters:** [\(clear all filters\)](#)

Patient ID:

Specimen date start: ☐ 06-Feb-2019

Import date start: ☐ 06-Feb-2019

Study:

Specimen date end: ☐ 06-Feb-2019

Import date end: ☐ 06-Feb-2019

Visit unit:

Received date start: ☒ 06-Feb-2019

☐ Include already assigned visits

Received date end: ☒ 06-Feb-2019

Select one or more patient visits:

Patient ID	Study	Visit	Specimen date/time	Received date	Import date	Clinic	Algorithm to start
999400021	704.0	11 Exp	05-Feb-2019 11:32	06-Feb-2019		V109 ...	Recent Exposure / Acute Infection AMP
999400054	704.0	12 Vst	05-Feb-2019 10:15	06-Feb-2019		V109 ...	Routine AMP
999400115	704.0	3 Vst	05-Feb-2019 09:43	06-Feb-2019		V109 ...	Routine AMP

## 2. Start workflows in HAWS

HIV Algorithm Workflow System

File View Reports Tools Help

**Common Tasks**

[Assign a patient visit to a workflow](#)

[All tasks](#)

[Select sample task list](#)

[Process assay task list](#)

[Submit redraw task list](#)

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[Result algorithm task list](#)

[Final report task list](#)

[Manage runs](#)

[View all workflows](#)

[Reassign specimen for a test](#)

Group: **VTN - HIV Vaccine Trials**

**Optional search filters:** [\(clear all filters\)](#)

Patient ID:

Study:

Visit unit:

Specimen date start: ☐ 06-Feb-2019

Specimen date end: ☒ 06-Feb-2019

Received date start: ☒ 06-Feb-2019

Received date end: ☒ 06-Feb-2019

Import date start: ☒ 06-Feb-2019

Import date end: ☒ 06-Feb-2019

☐ Include already assigned visits

Select one or more patient visits:

Patient ID	Study	Visit	Specimen date/time	Received date	Import date	Clinic	Algorithm to start
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999400054	704.0	12 Vst	05-Feb-2019 10:15	06-Feb-2019		V109 ...	Routine AMP
999400115	704.0	3 Vst	05-Feb-2019 09:43	06-Feb-2019		V109 ...	Routine AMP

## 2. Start workflows in HAWS

Select one or more patient visits:

(Highlight indicates already assigned visit or visit with multiple specimen dates.)

Patient ID	Study	Visit	Specimen date/time	Received date	Import date	Clinic	Algorithm to start
999400021	704.0	11 Exp	05-Feb-2019 11:32	06-Feb-2019		V109 ...	Recent Exposure / Acute Infection AMP
999400054	704.0	12 Vst	05-Feb-2019 10:15	06-Feb-2019		V109 ...	Routine AMP
999400115	704.0	3 Vst	05-Feb-2019 09:43	06-Feb-2019		V109 ...	Routine AMP

Starting Workflows

Starting workflows on selected visits...



Start workflow

[\(select all visits\)](#)

[\(deselect all visits\)](#)

Visits found: 3

Visits selected: 3

### 3. Start test runs

#### Common Tasks

[Assign a patient visit to a workflow](#)

[All tasks](#)

[Select sample task list](#)

[Process assay task list](#)

[Submit redraw task list](#)

[Receive redraw task list](#)

[Review assay task list](#)

[Result algorithm task list](#)

[Final report task list](#)

[Manage runs](#)

[View all workflows](#)

[Reassign specimen for a test](#)

Assay: (Any)

Kit: (Any)

(Any)

Available Abbott Architect HIV Ag/Ab Combo

Abbott AxSYM HIV Ag/Ab Combo

Abbott HIV-1/HIV-2 (rDNA)

11673 Abbott m2000 RealTime PCR HIV-1

Abbott Murex HIV-1.2.0

11677 Abbott Prism, Anti HIV-1/2, PSBC

11678 Alere Determine HIV-1/2 Ag/Ab Combo

bioMerieux Vironostika HIV Ag/Ab HIV 1/2

11679 bioMerieux Vironostika HIV Uni-Form II + O

Bio-Rad Geenius HIV 1/2 Confirmatory Assay

11680 Bio-Rad Genetic Systems HIV 1/2 Plus O

Bio-Rad Genetic Systems HIV-1

Bio-Rad Genetic Systems rLAV

Bio-Rad GenScreen HIV 1/2

Bio-Rad Genscreen Ultra HIV Ag-Ab HIV 1/2

Bio-Rad GS HIV Combo Ag/Ab EIA

Bio-Rad Multispot HIV-1/HIV-2 Rapid Test

Bio-Rad New Lav Blot II

HIV-1 Total Nucleic Acid Assay

Open Discretionary Test

OraQuick Rapid HIV-1 Antibody Test

Roche Amplicor HIV-1

Roche Amplicor Monitor HIV-1 Standard Ver 1.5

Roche Amplicor Monitor HIV-1 Ultrasensitive Ver 1.5

Roche COBAS Amplicor Monitor HIV-1 Standard Ver 1.5, with COBAS AmpliPrep

Roche COBAS Amplicor Monitor HIV-1 Ultrasensitive Ver 1.5, with COBAS AmpliPrep

Roche COBAS AmpliPrep/COBAS Taqman HIV-1, Version 1.0.

Roche COBAS AmpliPrep/COBAS Taqman HIV-1, Version 2.0.

Roche COBAS AmpliPrep/TaqMan HIV-1 Qualitative

### 3. Start test runs

#### Common Tasks

[Assign a patient visit to a workflow](#)

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[Select sample task list](#)

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[Final report task list](#)

[Manage runs](#)

[View all workflows](#)

[Reassign specimen for a test](#)

Assay: (Any)

Kit: (Any)

(Any)

Available Abbott Architect HIV Ag/Ab Combo

Abbott AxSYM HIV Ag/Ab Combo

Abbott HIV-1/HIV-2 (rDNA)

11673 Abbott m2000 RealTime PCR HIV-1

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bioMerieux Vironostika HIV Ag/Ab HIV 1/2

11679 bioMerieux Vironostika HIV Uni-Form II + O

Bio-Rad Geenius HIV 1/2 Confirmatory Assay

11680 Bio-Rad Genetic Systems HIV 1/2 Plus O

Bio-Rad Genetic Systems HIV-1

Bio-Rad Genetic Systems rLAV

Bio-Rad GenScreen HIV 1/2

Bio-Rad Genscreen Ultra HIV Ag-Ab HIV 1/2

Bio-Rad GS HIV Combo Ag/Ab EIA

Bio-Rad Multispot HIV-1/HIV-2 Rapid Test

Bio-Rad New Lav Blot II

HIV-1 Total Nucleic Acid Assay

Open Discretionary Test

OraQuick Rapid HIV-1 Antibody Test

Roche Amplicor HIV-1

Roche Amplicor Monitor HIV-1 Standard Ver 1.5

Roche Amplicor Monitor HIV-1 Ultrasensitive Ver 1.5

Roche COBAS Amplicor Monitor HIV-1 Standard Ver 1.5, with COBAS AmpliPrep

Roche COBAS Amplicor Monitor HIV-1 Ultrasensitive Ver 1.5, with COBAS AmpliPrep

Roche COBAS AmpliPrep/COBAS Taqman HIV-1, Version 1.0.

Roche COBAS AmpliPrep/COBAS Taqman HIV-1, Version 2.0.

Roche COBAS AmpliPrep/TaqMan HIV-1 Qualitative

### 3. Start test runs

Assay Results

Run ID: 11729

Kit: Open Discretionary Test

☐ Assigned to technician for testing

Tested by: E. Goecker (EG)

Test date: ☒ 20-Feb-2019

Samples:

Specimen	Patient ID	Wf ID	T	R	A
H0F15GS5-01	999400054	883...			

Close

Patient ID: 999400054

Visit: 12 Vst

Draw date: 05-Feb-2019

Global specimen ID: H0F15GS5-01

Other specimen ID:

Comments:

☐ Do not report ☐ Do not export to SCHARP

Final result:

Entered by:

Entered date:

Commit results

Approved by:

Approved date:

Approve results

Assay name: Low Level HIV-1 RNA PCR

Analyte:

- HIV-1 Antibody
- HIV-2 Antibody
- HIV-1 and HIV-2 Antibody
- HIV-1 Antigen
- HIV Antibody and Antigen
- HIV-1 RNA
- HIV-1 DNA
- HIV-1 RNA and DNA (TNA)
- HIV-2 RNA
- HIV-2 DNA
- HIV-2 RNA and DNA (TNA)

### 3. Start test runs

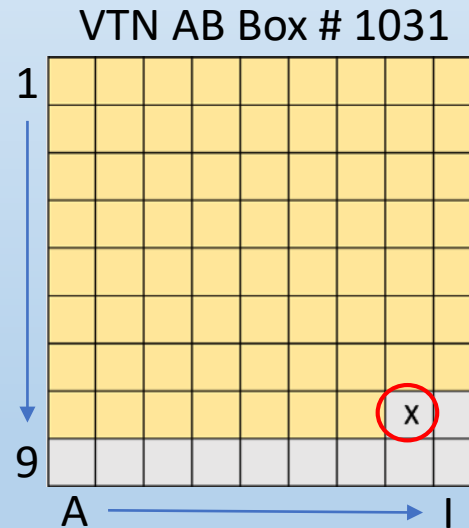
#### Specimen Locator

<b>Run: 11,681</b>		<b>Test: Enzyme Immuno Assay : Abbott Architect HIV Ag/Ab Combo</b>					
		<b>Rec'd Date</b>					
<b>Patient Id</b>	<b>Visit</b>	<b>Coll. Date</b>	<b>Testing Lab</b>	<b>Global ID</b>	<b>Other Spec ID</b>	<b>Sample Type</b>	<b>Storage Location</b>
999400021	11.0 Exp	05-Feb-2019	06-Feb-2019	K0F15GSQ-01		BLD/EDT/PL1	VTN AB / HONG KONG / BOX 1031 / 008,H
999400054	12.0 Vst	05-Feb-2019	06-Feb-2019	H0F15GS5-01		BLD/EDT/PL1	VTN AB / HONG KONG / BOX 1031 / 008,I
999400115	3.0 Vst	05-Feb-2019	06-Feb-2019	F0F15GS1-01		BLD/EDT/PL1	VTN AB / HONG KONG / BOX 1031 / 009,A

### 3. Start test runs

## Specimen Locator

Run: 11,681		Test: Enzyme Immuno Assay : Abbott Architect HIV Ag/Ab Combo					
		Rec'd Date					
Patient Id	Visit	Coll. Date	Testing Lab	Global ID	Other Spec ID	Sample Type	Storage Location
999400021	11.0 Exp	05-Feb-2019	06-Feb-2019	K0F15GSQ-01		BLD/EDT/PL1	VTN AB / HONG KONG / BOX 1031 / 008,H
999400054	12.0 Vst	05-Feb-2019	06-Feb-2019	H0F15GS5-01		BLD/EDT/PL1	VTN AB / HONG KONG / BOX 1031 / 008,I
999400115	3.0 Vst	05-Feb-2019	06-Feb-2019	F0F15GS1-01		BLD/EDT/PL1	VTN AB / HONG KONG / BOX 1031 / 009,A





## 4. Input of test results

Assay Results

Run ID: 11681

Kit: Abbott Architect HIV Ag/Ab Combo

☐ Assigned to technician for testing

Tested by: G. Daza (GD)

Test date: ☒ 06-Feb-2019

Samples:

Specimen	Patient ID	Wf ID	T	R	A
K0F15GSQ-01	999400021	880...	T	R	A
H0F15GS5-01	999400054	880...	T	R	A
F0F15GS1-01	999400115	880...	T	R	

Patient ID: 999400054

Visit: 12 Vst

Draw date: 05-Feb-2019

Global specimen ID: H0F15GS5-01

Other specimen ID:

Comments:

☐ Do not report ☐ Do not export to SCHARP

Final result: Non-reactive

Entered by: G. Daza (GD)

Entered date: 06-Feb-2019

Approved by: E. Goecker (EG)

Approved date: 06-Feb-2019

S/CO: 0.56

Commit results

De-approve results

Close

## 4. Input of test results

### Completed Run Worksheet

Run ID: 11,681      Test Date: 06-Feb-2019      Tested By: G. Daza

Approved By/Date:

*eg 06 Feb 2019*

Test: Enzyme Immuno Assay : Abbott Architect HIV Ag/Ab Combo

Patient ID	Visit	Global ID	Other Spec ID	Coll. Date	S/CO	Final Result	Entered By
999400021	11.0 Exp	K0F15GSQ-01		05-Feb-2019	0.11	Non-reactive	G. Daza
999400054	12.0 Vst	H0F15GS5-01		05-Feb-2019	0.56	Non-reactive	G. Daza
999400115	3.0 Vst	F0F15GS1-01		05-Feb-2019	0.08	Non-reactive	G. Daza

## 4. Input of test results

New tests  
ordered

Patient ID:  Workflow ID:  Study:  ☐ Do not export ☐ Do not report

Algorithm:

Results

Test name	Kit name	Visit	Result	Test date	Run ID	Detail
EIA 1	Abbott Architect HIV Ag/Ab Combo	12 Vst	Reactive	16-Feb-2019 18:03	11719	S/CO[5.10]
RNA PCR		12 Vst				
Geenius		12 Vst				

Proposed result:

Final result:

Blinded result:  Unblinded result:

Diagnosis date: ☐ 19-Feb-2019

Approved by:

Date approved:

Comments:

The final result cannot be set at this time, because the algorithm has not yet reached the ResultAlgorithm step.

## 4. Input of test results

Algorithm Summary

Patient ID: 999400054 Workflow ID: 88364 Study: 704.0 ☐ Do not export ☐ Do not report

Algorithm: Routine AMP

Results Tasks Discretionary actions

Action Type Description

Start Discretionary Test

Available assay types:

- Assay
- Multi-Spot Assay
- RNA PCR
- Enzyme Immuno Assay
- Western Blot Bio-Rad New Lav Blot II
- DNA PCR
- Western Blot Bio-Rad Genetic Systems HIV-1
- Abbott Prism
- Bio-Rad Geenius HIV 1/2 Confirmatory Assay
- HIV-1 Total Nucleic Acid Assay
- Open Discretionary Assay

Assay name (default can be changed): EIA 1

# 5. Algorithm interpretation and summary

Patient ID:  Workflow ID:  Study:  ☐ Do not export ☐ Do not report

Algorithm:

Results

Test name	Kit name	Visit	Result	Test date	Run ID	Detail
EIA 1	Abbott Architect HIV Ag/Ab Combo	11 Exp	Non-reactive	06-Feb-2019 16:27	11681	S/CO[0.11]
RNA PCR	Abbott m2000 RealTime PCR HI...	11 Exp	Not Detected	16-Feb-2019 18:00	11718	Copies/mL[<40]

Proposed result:

Final result:

Blinded result:

Unblinded result:

Diagnosis date:

Approved by:

Date approved:

Comments:

The final result cannot be approved at this time, because it is not yet set.

# 5. Algorithm interpretation and summary

Patient ID: 999400021 Workflow ID: 88223 Study: 704.0 ☐ Do not export ☐ Do not report

Algorithm: Recent Exposure / Acute Infection AMP

Results Tasks Discretionary actions

Test name	Kit name	Visit	Result	Test date	Run ID	Detail
EIA 1	Abbott Architect HIV Ag/Ab Combo	11 Exp	Non-reactive	06-Feb-2019 16:27	11681	S/CO[0.11]
RNA PCR	Abbott m2000 RealTime PCR HI...	11 Exp	Not Detected	16-Feb-2019 18:00	11718	Copies/mL[<40]

Proposed result: HIV-1 and HIV-2 Not Detected

Final result: HIV-1 and HIV-2 Not Detected

Blinded result: No evidence of infection with HIV-1 or HIV-2. Unblinded result:

Diagnosis date: 16-Feb-2019

Approved by: E. Goecker (EG)

Date approved: 16-Feb-2019

Comments:

## 6. Infection status report - Blinded

### HVTN: Blinded HIV-1 Infection Status Report

#### Routine AMP (HVTN704 / HPTN085)

---

**Participant:** 999400115

**Protocol:** HVTN 704.0

**CRS Contact:** Julie McElrath  
FHCRC / University of Washington  
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Seattle, WA 98104

**Phone:** 206-667-2344

**Fax:** 206-667-2299

**Email:** VTN.Site.30331.HIV.Test.Result  
s@hvtn.org

---

**Visit:** 3.0

**Visit Type:** Routine

**Collection Date:** 05-Feb-2019

**Collection Time:** 09:43

---

**Results:** Individual test results blinded per protocol. See Summary interpretation below.

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Comments:

**Summary:** No evidence of infection with HIV-1 or HIV-2.

## 6. Infection status report - Unblinded

Visit: 10.0

Visit Type: Post-Study

Collection Date: 28-Jan-2019

Collection Time: 14:20

### Results:

#### ECR (EIA/CIA/Rapid) Results

Kit Name	Result
Bio-Rad GS HIV Combo Ag/Ab EIA	Non-reactive
Abbott Architect HIV Ag/Ab Combo	Reactive
Alere Determine HIV-1/2 Ag/Ab Combo	Reactive for HIV Antibody

#### RNA Results

Kit Name	Copies/mL	Result
Abbott m2000 RealTime PCR HIV-1	< 40	Not Detected

#### Geenius Results

Kit Name	gp36	gp140	p31	gp160	p24	gp41	CTRL	Result
Bio-Rad Geenius HIV 1/2 Confirmatory Assay	-	-	-	-	-	-	+	HIV Negative

Comments:

**Summary:** No evidence of infection with HIV-1 or HIV-2. These results are consistent with vaccine-induced sero-reactivity, if participant received vaccine product, or these results may be due to non-specific serological cross-reactivity.



# Data export

- Individual algorithm results may be exported for evaluation by a protocol specific adjudicator to confirm appropriate interpretation
- Cumulative data export files are generated for SCHARP

# Improved Turnaround Time with HAWS

- HAWS has multiple turnaround time (TAT) tracking report options allowing the lab to monitor performance
- Turnaround time varies with the visit type
- Using HAWS, the UW is able to test hundreds of samples per week →
  - >95% of routine visits reported in 1 day
  - >95% of recent exposure visits reported in 2 days
  - Typical TAT for more complicated algorithms is 3 days

# Looking to the future of HAWS

1. Multiple networks to use and influence development of HAWS
2. Local administrators to define testing algorithms within HAWS
3. Interact and retrieve data from cloud based/web programs
  - e.g. Web LDMS

# Potential Future Uses

1. Fiebig staging of new HIV infections
2. HIV diagnostic testing
3. HIV diagnostic testing for other networks, working in conjunction with LDMS for comprehensive specimen management

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## HVTN Lab Operations Staff

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