



Manual



HAWS User Manual

HAWS
Version 7.2
Windows
LS.0007

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Document ID: LS.0007
Application version: 7.2
Document version: N/A
Last reviewed or updated: 10-Dec-2025
Effective: 10-Dec-2025

Summary

HAWS (The HIV Algorithm Workflow System) is an application for managing the workflow and data capture processes associated with HIV studies. HAWS walks the user through a series of steps for a patient visit, collecting assay results from the user, managing requests for specimen redraws, and ultimately determining the final result of the testing work for the patient visit.

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Getting started with HAWS

This section will get you acquainted with HAWS.

What is HAWS?

HAWS (The HIV Algorithm Workflow System) is an application for managing the workflow and data capture processes associated with HIV studies. HAWS walks the user through a series of steps for a patient visit, collecting assay results from the user, managing requests for specimen redraws, and ultimately determining the final result of the testing work for the patient visit.

HAWS works by assigning *algorithms* to patient visits. Each algorithm determines what specimens need to be tested and what assays need to be run for the visit. Depending on the results of each assay, the algorithm may assign additional assays to be run. In this way, HAWS acts like a flow chart, guiding the user from a visit to a final result, helping them keep track of individual results and the next step needed in the process.

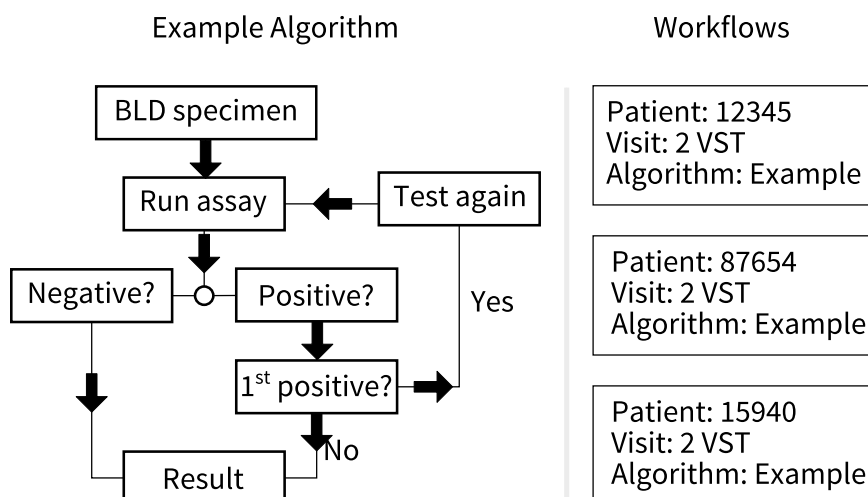
HAWS also includes many other tools useful for completing HIV testing work, such as the ability to generate final reports for several patient visits at once, print listings of specimens to be tested along with their storage locations, and the ability to interact with data stored in LDMS.

What are algorithms and workflows

An *algorithm* is the logic for processing a patient visit; a *workflow* is a visit that is currently being processed by an algorithm.

Algorithms are defined by network leadership and implemented in HAWS by Frontier Science. Users cannot create new algorithms, nor can they modify existing algorithms. An algorithm may define such things as what assays need to be run for certain specimen types. For example, if a visit included a blood specimen, the algorithm would define what assay(s) needs to be run for that specimen. Depending on the results of the assay, the algorithm may define additional tests. This might happen, for example, if a specimen tested positive and a second test is needed to confirm the positive result.

A workflow is an *instance* of an algorithm. When a user selects a visit to process in HAWS, they select the algorithm to use and the workflow is created. Thus you can create several workflows using the same algorithm.

Figure 1: Example algorithm and workflows based on it

An example algorithm (left) and workflows for patient visits using the logic from the algorithm (right).

While a workflow is active, HAWS will guide you to the text step in the algorithm's logic automatically. Using the example, if a workflow orders a test and the result is a positive, HAWS will automatically determine if this was the first positive for the workflow and, if yes, automatically reassign the assay to be run again.

LDMS and HAWS

HAWS will pull participant, visit, and specimen information from your LDMS database. The sync to the LDMS database is configured by User Support upon installation or upgrade.

Typically data from LDMS is populated in HAWS automatically and the process will be transparent. If you do need to refresh data from LDMS manually, click **Tools > Refresh from LDMS** from the HAWS menu bar.

Getting HAWS

HAWS will typically be installed by HAWS User Support. This is usually done using a remote connection to your computer. Not only will HAWS User Support install HAWS, they will also perform general configuration for you so that your laboratory can start using HAWS right away.

HAWS User Support will ask you for specific information about your laboratory, such as contact information and where you want files stored on your server. This information will be used to initially configure HAWS. Most of these settings can be updated later by your laboratory. A backup of the database should occur prior to the upgrade to a new version or the re-install of the database.

Getting help

HAWS User Support is available 24 hours per day, 7 days per week. HAWS User Support can answer questions about using HAWS and, if needed, connect remotely to your computer to assist with technical issues. Additionally, a link to the user manual can be accessed from the Help menu.

HAWS User Support by telephone +1 716 834 0900 extension 7311

HAWS User Support by email haws@fstrf.org

More information and support resources are available on the [LDMS website](#).

Supported assays

The following assays and kits are supported by HAWS.

| Assays | Supported kits |
|--|--|
| Abbott Prism | Abbott Prism, Anti HIV-1/2 |
| Bio-Rad Geenius HIV 1/2 Confirmation Assay | Bio-Rad Geenius HIV 1/2 Confirmation Assay |
| Alere | Alere Determine HIV-1/2 Ag/Ab Combo Alere HIV Combo Determine HIV Early Detect Determine HIV Early Detect (Non-CE) |
| DNA PCR | Frozen Whole Blood DNA ddPCR assay Roche Amplicor HIV-1 Roche COBAS AmpliPrep/TaqMan HIV-1 Qualitative |
| Enzyme Immuno Assay | Abbott Architect HIV Ag/Ab Combo Abbott AxSYM HIV Ag/Ab Combo Abbott HIV-1/HIV-2 (rDNA) Abbott Murex HIV-1.2.O bioMerieux Vironostika HIV Ag/Ab HIV 1/2 bioMerieux Vironostika HIV Uni-Form II + O Bio-Rad Genetic Systems HIV 1/2 Plus O 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 Toyo Anti-HIV ½ |

| Assays | Supported kits |
|--|--|
| HIV-1 Total Nucleic Acid Assay | HIV-1 Total Nucleic Acid Assay |
| Multi-Spot Assay | Bio-Rad Multispot HIV-1/HIV-2 Rapid Test |
| OraQuick | OraQuick Rapid HIV-1 Antibody Test |
| RNA PCR | Abbott Alinity m HIV-1 RT-PCR Abbott m200 RealTime PCR HIV-1 Roche Amplicor Monitor HIV-1 Standard Ver 1.5 Roche Amplicor Monitor HIV-1 Ultrasensitive Ver 1.5 Roche Cobas 5800/6800/8800 System HIV-1 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 UW Developed HIV-1 RNA Real-Time RTPCR UW Developed HIV-2 RNA PCR |
| SD Bioline | SD Bioline HIV-1/2 3.0 |
| Western Blot Bio-Rad Genetic Systems HIV-1 | Bio-Rad Genetic Systems HIV-1 |
| Western Blot Bio-Rad New Lav Blot II | Bio-Rad New Lav Blot II |

Related tasks

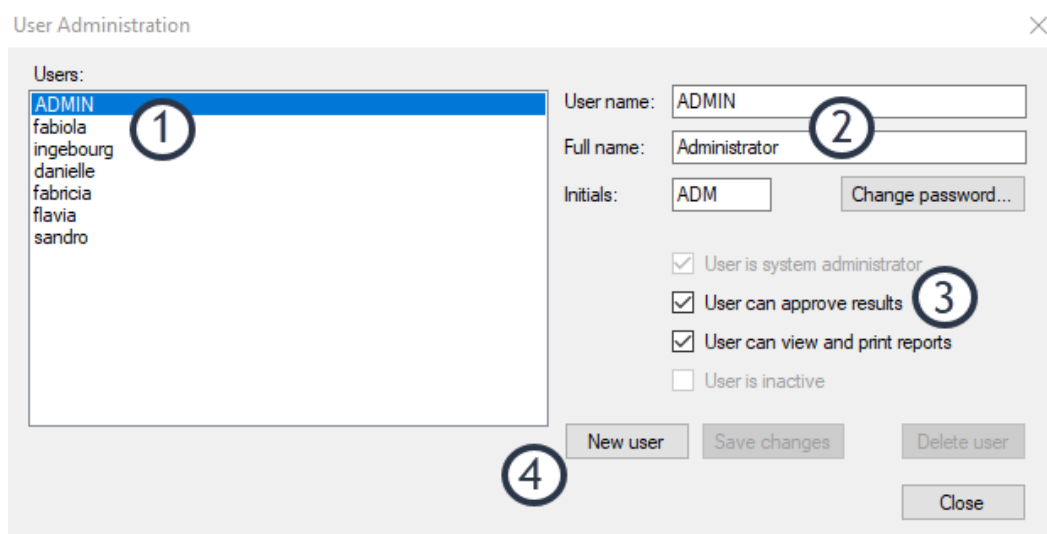
[Creating a new run](#) on page 28

Configuring HAWS

This section will describe the various configuration options and features available in HAWS.

User management in HAWS


HAWS is user-based. In order to use HAWS, you must login using your own unique user account. Your user account determines what you are permitted to do in HAWS, and HAWS tracks what user completes certain actions.

Figure 2: The User Administration window

(1) existing users, (2) information for currently selected user, (3) permissions for currently selected user, (4) create a new user

There are three types of permissions that users can have in HAWS:


- | | |
|-----------------------------------|--|
| Administrator | An administrator can make changes to other user accounts, create and inactivate users, and change configuration settings in HAWS. The only setting that administrators cannot change is their own status as an administrator. This prevents users from accidentally removing all administrators. |
| Can approve results | Users with this permission can complete the <i>result algorithm task</i> and approve assay results. |
| Can view and print reports | Users with this permission can generate final reports for workflows. |

 **Note:** Administrators don't inherently have the ability to approve results and generate reports; these are separate concepts in HAWS.

HAWS User Support will typically create the necessary users for you when installing HAWS. If no users were created for you, the default user is `admin` with the password `admin`. To prevent users from logging in as the `admin` account to complete normal work, the `admin` account should be set to inactive once you have created at least one other system administrator.

Creating new users

Prerequisites

 **Note:** Creating, removing, and modifying other user accounts requires system administrator permissions. Non-system administrators can only modify certain properties for their own user account.

Steps

1. Click **Tools > User Administration** from the HAWS menu bar.
2. Click the **New user** button.
3. Enter the new user's user name into the **User name** text box.
The user name is not case sensitive. The user name must also be unique among all users, including those that have already been deleted.
4. Enter the new user's full name into the **Full name** text box.
5. Enter the new user's initials into the **Initials** text box.
6. Select any permissions that should be assigned to the user.

Option

system administrator

Can create, modify, and remove other users

Can approve results

User can approve assay results and complete the *result algorithm* task

Can view and print reports

User can complete the *final report task* and print bulk reports

Result

New users will have the same password as their user name by default. For example, a user with the user name `ROBERT` will have the default password `robert` (lower case).

After you are finished

The new user should change his or her password after logging in for the first time. This is done by selecting **Tools > User administration** from the HAWS menu bar, and then clicking the **Change password** button.

Modifying users

Steps

1. Click **Tools > User Administration** from the HAWS menu bar.
2. Select the user to modify from the list of users on the left.
3. Modify user information as needed.
 - Regular users can only change their user name, full name, and password
 - Administrators can change user permissions
 - Administrators can inactivate the selected users. Inactive users cannot log on to HAWS, but will still be available for selection in drop-down lists (e.g. selecting the technician for an assay run)



Note: While it is possible to delete users, it is recommended that users be inactivated in case the user's account is needed in the future.

4. After all changes are made, click the **Save** button.

Options window

The **Options** window allows the user to configure several general HAWS settings. The **Options** window is accessed by clicking **Tools > Options** from the HAWS menu bar.



Note: During installation, HAWS User Support will have configured these settings for you.

Figure 3: The Options window

(1) location where exports will be generated, (2) location where final workflow reports will be generated, (3) location for HAWS log files, (4) location where backup files will be generated

The screenshot shows the 'Options' dialog box with the following settings and callouts:


- Export base folder:** C:\strf-DEV\HAWS\Export (Callout 1)
- Reports base folder:** C:\strf-DEV\HAWS\Reports (Callout 2)
- HAWS data folder:** C:\strf-DEV\HAWS\Data (Callout 3)
- ☒ Search for samples not in storage (Callout 4)
- Automatically lock HAWS if idle for (in minutes):** 30 (Callout 5)
- Backup Settings:**
 - Folder (on server):** C:\strf-DEV\HAWS\Backup (Callout 5)
 - Retention days:** 5

Buttons: OK, Cancel, and a close button (X) in the top right corner.

The following settings can be changed in the **Options** window:

| | |
|----------------------------|---|
| Export base folder | This is the directory where SCHARP export files and adjudication export files will be saved. Files will be placed in sub-directories in the export base folder. |
| Reports base folder | This is the directory where workflow reports will be saved. |
| HAWS data folder | This is the location where log files generated by HAWS will be stored. |

| | |
|--|---|
| Search for samples not in storage | If enabled, samples that have not been stored in the LDMS Storage task will be displayed. |
| Automatically lock HAWS if idle | This is the amount of time (in minutes) after which HAWS will automatically lock and require a user name and password. To disable this feature, set this number to 0 |
| Backup settings | This is the directory on the HAWS server where automatically generated backup files of HAWS data will be created, as well as the number of days the backup files will be retained. The oldest files will be deleted after the set retention days (default: 7 days). |

 **Note:** Because the HAWS backup files are stored on the HAWS server, it is important that you manually copy these files to a safe location that is not on the HAWS server. It is recommended that you do this once per week.

Related concepts

[Backup management](#) on page 22

Related tasks


[Export reports](#) on page 52

Export reports are tab-delimited text files that are intended to be sent to SCHARP.

[Creating unblinded EOS/EOX reports](#) on page 51

[Batch printing final reports](#) on page 50

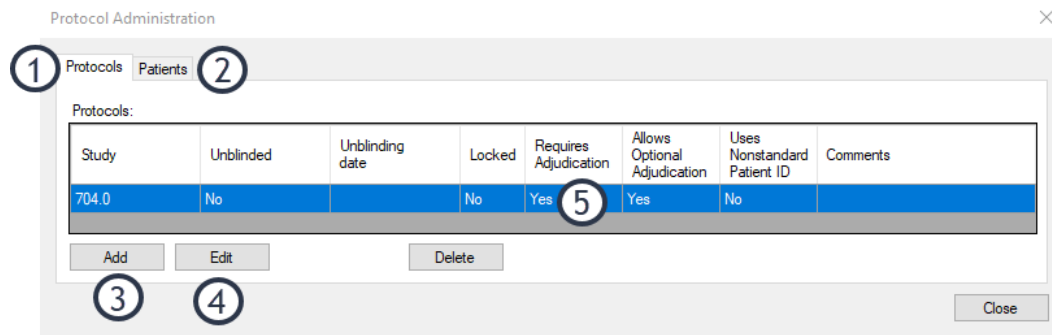
Protocol Administration

 **Note:** Only users with system administrator privileges can access **Protocol Administration**.

The **Protocol Administration** window is used to manage what protocols and patients are blinded and unblinded. Protocol administration is accessed by clicking **Tools > Protocol Administration** from the HAWS menu bar.

Figure 4: The Protocol Administration window

(1) add/view/modify protocols, (2) add/view/modify unblinded patients, (3) add new protocol to HAWS, (4) modify selected protocol, (5) list of protocols entered into HAWS



For the evaluation of sero-reactivity (EOS), evaluation of sero-reactivity recent exposure (EOX), and post-study (POS) algorithms, the final workflow report can be generated as either blinded or unblinded. Here is how the two versions differ:

- A blinded report shows the overall final workflow result, but does not include individual test results.
- An unblinded report shows both the final workflow result and individual test results.

The routine (VST) and recent exposure (EXP) algorithms always produce blinded reports. The infected testing (INF) algorithm essentially produces an unblinded report because it is a report of an individual RNA PCR test.

To determine whether an HIV Infection Status Report should be produced as blinded or unblinded, HAWS checks whether the entire protocol has been unblinded. If the entire protocol has not been unblinded, HAWS will check if the specific Patient ID for this algorithm has been unblinded. If neither of these are the case, then HAWS will produce a blinded report.

Changing protocol adjudication settings

Steps

1. On the **Tools** menu, click **Protocol Administration**.
2. Select the study to be modified, and then click **Edit**.
3. Modify the Requires adjudication and Allows optional adjudication settings as needed.

Requires adjudication

Users will not be able to approve a final result for a workflow until an adjudication report has been generated and a diagnosis date has been set.

Allows optional adjudication

Users will be able to generate an adjudication report at any time during the workflow, and may optionally set a diagnosis date.

4. Click **OK**.
5. In the **Protocol Administration** window, click **Close**.

Related tasks

[Generating adjudication report](#) on page 52

Unblinding a protocol**Prerequisites**

Note: To access the **Protocol Administration** window, you must have system administrator privileges.

Steps

1. On the **Tools** menu, click **Protocol Administration**.
2. On the **Protocols** tab, click **Add**.

The **Edit Protocol Information** window will open.

Protocol: 704.0

Unblinded date: 13-Aug-2019

☐ Locked

☒ Requires adjudication

☒ Allows optional adjudication

☐ Uses nonstandard patient ID format

Comments:

OK Cancel

3. In the **Protocol** box, enter the protocol number to be unblinded.
4. In the **Unblinded date** box, enter or select the date that the protocol was un-blinded.
5. Optional: If you want to exclude any new data generated for this protocol from SCHARP export files, select the **Locked** option.
6. Click **OK**.

Result

After completing these steps, the unblinded study will be added to the list on the **Protocols** tab in the **Protocol Administration** window. It can be modified by selecting it and clicking the **Edit** button. It can be removed by selecting it and clicking the **Delete** button.

Unblinding patients

Prerequisites



Note: To access the **Protocol Administration** window, you must have system administrator privileges. You must also have patient information file provided by SCHARP.

Steps

1. On the **Tools** menu, click **Protocol Administration**.
2. Select the **Patients** tab.
3. Click the **Open file** button.
4. Select the patient information file provided by SCHARP.
The list of patients to be unblinded from the file will appear in the list on the **Patients** tab. This list should be reviewed for accuracy before continuing with the unblinding.
5. Click the **Unblind selected patients** button.

Configuring the test now storage location

Prerequisites



Note: You will need system administrator privileges to access the **Storage Administration** window.

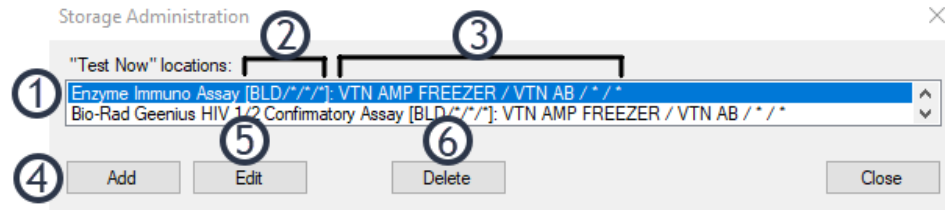
Background

A *test now* location is a location in the LDMS storage task associated with an assay in HAWS. If you create a workflow for a visit in HAWS and that visit has specimens in the *test now* location in LDMS, those specimens will automatically be assigned to an assay, allowing you to bypass the *select sample task*.

Steps

1. Click **Tools > Storage Administration** from the HAWS menu bar.
The **Storage Administration** window will open.

Figure 5: The Storage Administration window

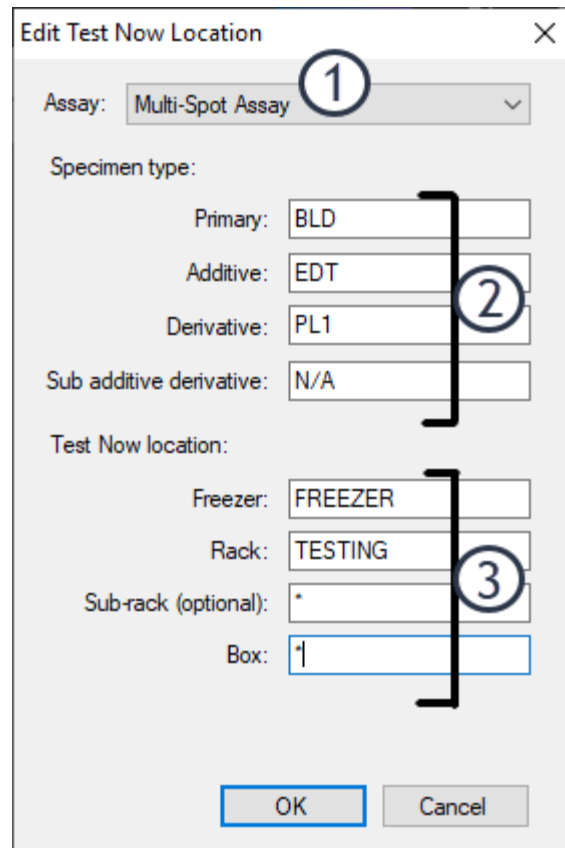


(1) assay to be assigned, (2) from left to right: primary type, additive, derivative, sub additive/derivative, (3) from left to right: LDMS freezer, level, sub-level, and container, (4) create new *test now* location, (5) modify selected *test now* location, (6) remove selected *test now* location

2. Click the **Add** button.

The **Edit Test Now Location** window will open.

Figure 6: The Edit Test Now Location window



(1) assay to be assigned, (2) type of specimens to be assigned assay, (3) LDMS storage location

3. Select the assay to be automatically assigned to specimens in this storage location from the **Assay** list.
4. In the **Derivative** box, specify the LDMS derivative code of specimens to be assigned to selected assay.



Note: While the derivative is required, the specimen type information is not currently used by HAWS.

5. Required: Specify the exact name of the freezer to be assigned the selected assay.
6. Specify the **Rack**, **Sub-rack**¹ and **Box**.²
 - If you want a specific storage location, you can specify it by name.
 - If you want to select all sub-levels (for example, all racks in a freezer), enter * into the text box. This is used to specify all racks, sub-racks, and boxes in the VTN AB freezer as this *test now* location.
7. Click the **OK** button.

Result

The new *test now* location will be created and added to the **"Test Now" locations** list. To modify a *test now* location after it has been created, select it from the **"Test Now" locations** list, and then click the **Edit** button. To remove a *test now* location, select it, and then click the **Delete** button.



Note: Deleting a *test now* location means that specimens in the storage location will no longer automatically be assigned an assay. The storage location in LDMS will not be modified or removed.

Related information

<http://www.ldms.org/resources/ldms/codes/>

Location administration

The **Location Administration** window has two purposes:

- Set the contact information for your laboratory.
- View and modify clinics that have been manually added by your laboratory to HAWS or clinics that have been loaded from LDMS.



Note: For clinics that are loaded from LDMS, the LDMS clinic ID cannot be edited.

¹ A *rack* and *sub-rack* are known as levels and sub-levels in LDMS.

² A *box* is known as a container in LDMS.

Figure 7: The Location Administration window

| Clinic Name | LDMS ID |
|-------------------------|---------|
| Instituto de Pesq... | V287 |
| QC | V999 |
| Fundación Hués... | V850 |
| Inst de Pesquisa ... | V721 |
| Rosario | V894 |
| HGNI DST/AIDS | V748 |
| Centro de Pesqui... | V860 |
| Manaus | V781 |
| Centro de Refere... | V845 |
| Federal Universit... | V741 |
| Sao Paulo - Paca... | V888 |
| Centro Medico S... | V710 |
| University of Roc... | V123 |
| University of Illino... | V101 |

Clinic name: Instituto de Pesquisa Clinica Evandro Cha
 LDMS clinic ID: V287
 Contact name: Valdeia Veloso
 Address 1: Avenida Brasil, 4365
 Address 2: Manguinhos CEP 21040-360
 City: Rio de Janeiro
 State: Brazil Zip code:
 Country:
 Phone number: 55 21 2270 7064
 Fax number:
 E-mail: ptn.site.12101.HIV.Test.Results@hvtm.org

New clinic Save changes Delete clinic

Close

(1) clinics already added to HAWS, (2) information for selected clinic, (3) save changes to selected clinic, (4) view and edit address of current lab



Note: The **New Clinic** and **Delete Clinic** options on the Location Administration screen are no longer used, as clinic data comes directly from LDMS.

Your laboratory's contact information as specified in will be printed at the top of final workflow reports generated by your laboratory.

To access **Location Administration**, click **Tools > Location Administration** from the HAWS menu bar. A location can be modified by selecting it from the **Clinics** list on the left, modifying its information on the right side of the window, and then clicking the **Save changes** button. If the location is an LDMS clinic, you will not be able to modify the **LDMS clinic ID** text box for the clinic.

Holiday administration

The **Holiday Administration** window allows you to specify given days during the calendar year that are considered holidays at your laboratory. This

ensures that days that your laboratory is not operating will be subtracted from the calculations in the Turn Around Time reports.


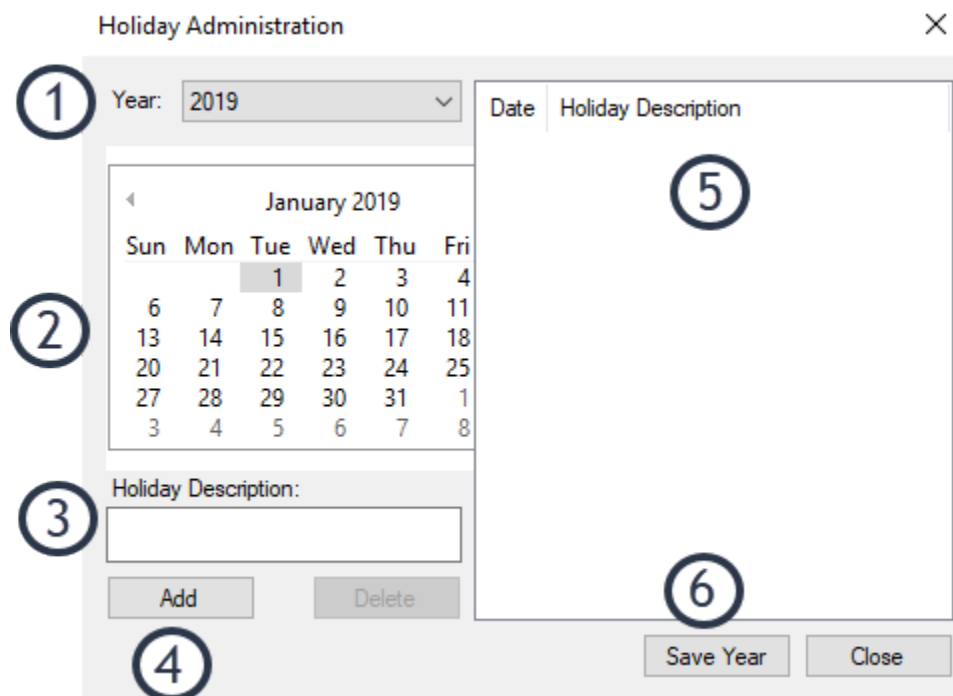
 **Note:** HAWS does *not* automatically add any holidays.

Figure 8: The Holiday Administration window




The screenshot shows the 'Holiday Administration' window. It features a 'Year' dropdown menu (1) set to '2019'. Below it is a calendar for 'January 2019' (2) with the 1st of January highlighted. A 'Holiday Description' text box (3) is located below the calendar. At the bottom left are 'Add' and 'Delete' buttons (4). On the right side, there is a table with columns 'Date' and 'Holiday Description' (5). At the bottom right are 'Save Year' and 'Close' buttons (6).

(1) select year to add/view holidays, (2) select day for new holiday, (3) enter name for new holiday, (4) add selected date and name as new holiday, (5) holidays already added for the selected year, (6) save changes to current year

Access the **Holiday Administration** window by clicking **Tools > Holiday Administration** from the HAWS menu bar.

To add a holiday:

1. Select a year from the **Year** list.
2. Select a date from the calendar control.
3. Enter a name for the holiday into the **Holiday Description** text box.
4. Click the **Add** button.
5. Click the **Save Year** button

 **Note:** HAWS does not allow annual or recurring holidays. If a holiday occurs every year, you will need to add it each year.

Default algorithm setup

Setting up custom default algorithms for various Study/VID combinations can save you a lot of time, and give you additional flexibility.

Steps


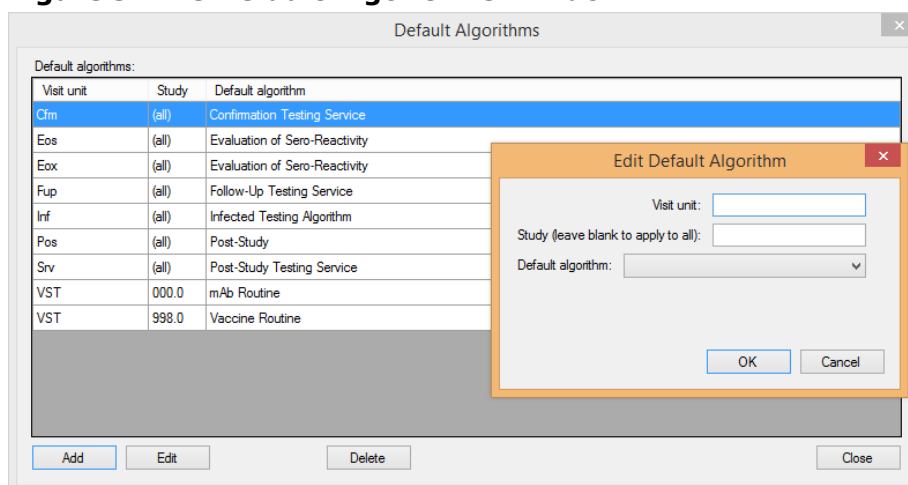
1. From the **Tools** menu, click **Default algorithms**.
 2. Click **Add**.
 3. Enter the visit unit you wish to set a default algorithm for.
 4. Set **Study** to the desired study.
-  **Note:** Specifying a **Study** value allows for the ability to, for the same visit type, use Algorithm A for one study and Algorithm B for another study. Alternatively, you can leave **Study** blank which will allow the algorithm assignment to be applied to all studies without a specific algorithm assignment.

Figure 9: The Default Algorithms Window



Default assay kit assignment

A default assay kit allows you to define the kit that can be used for a specific assay on a specific algorithm

If an algorithm has a kit assignment, workflows using that algorithm will limit the defined assay to using the selected kit. If that kit is not selected for the assay, the specimens will not be available to add to the run.

Example default kit assignment

If you set the following kit assignment, specimens assigned the EIA 1 assay on workflows using the routine algorithm will only be displayed if the Bio-Rad 1/2+O kit is selected. If another kit for the assay is selected, the specimens will not be available to add to the assay run.


| Algorithm | Assay | Kit | Study |
|-----------------|-------|--|-------|
| Vaccine Routine | EIA 1 | Bio-Rad Genetic Systems HIV 1/2 Plus O | |

Adding kit assignments

Add an assay kit default to restrict kit selection available for individual algorithms and assays.

Steps

1. On the **Tools** menu, click **Kit assignment**.
2. Click **Add**.
3. Enter the following information.
 - In the **Algorithm** box, select the algorithm to which this default should be applied.
 - In the **For tests starting with** box, select an assay.
 - In the **Default kit** box, select the kit you want to use.
 - In the **Study** box, select the study you want to use.


 **Note:** Specifying a Study value allows for the ability to, for the same algorithm type and test type, use test A for one study, test B for another study. Alternatively, you can leave the Study box blank as a **wildcard** option which will allow which will allow the kit assignments to be applied to all studies without a specific kit assignment.
4. Click **OK**.

Modify kit assignment

You can modify the kit of an existing kit assignment.

Steps

1. On the **Tools** menu, click **Kit assignment**.
2. Click the kit assignment you want to change.
3. Click **Edit**.
4. In the **Default kit** box, change the kit assigned.

 **Note:** Only the kit can be changed. If you need to change the algorithm or assay, delete the kit assignment and create a new one instead.
5. Click **OK**.

Delete kit assignment

You can remove an existing kit assignment.

Steps

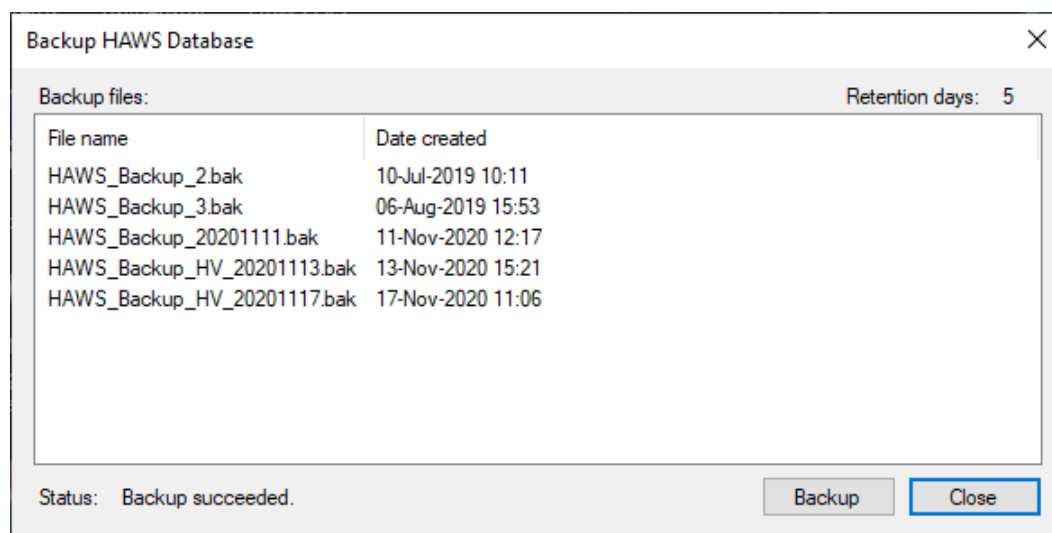
1. On the **Tools** menu, click **Kit assignment**.
2. Click the kit assignment you want to delete.
3. Click **Delete**.
4. When you see the "Are you sure you want to permanently delete the default kit assignment" message, click **Yes**.

Backup management

HAWS will automatically check if a backup of its internal database has been created for the current date every time you start or exit HAWS. If a backup was not created, one will be created automatically. The HAWS server installer includes a warning text reminding the user to backup HAWS databases before running the installer.

Backup files will be stored in the backup location on the HAWS server. One day's backup per file is saved and, by default, seven consecutive days are saved in the backup directory. Each day, the oldest will be removed as a newer one is created. Both the backup location and the number of days backups will be retained can be changed in the **Options** window.

Figure 10: The Backup window



Important: The HAWS backup location is typically on the same computer where HAWS is installed. This means that if something happens to the computer, the backup files will be lost. It is important to regularly copy automatic backups to a safe location, such as a CD-RW.

Users with system administrator privileges can manually create a backup file. To manually create a backup file:

1. Click **Tools > Backup** from the HAWS menu bar.
2. Click the **Backup** button.

Related concepts

[Options window](#) on page 11

Steps for Verifying a Backup File

To verify a backup file, perform the following steps:

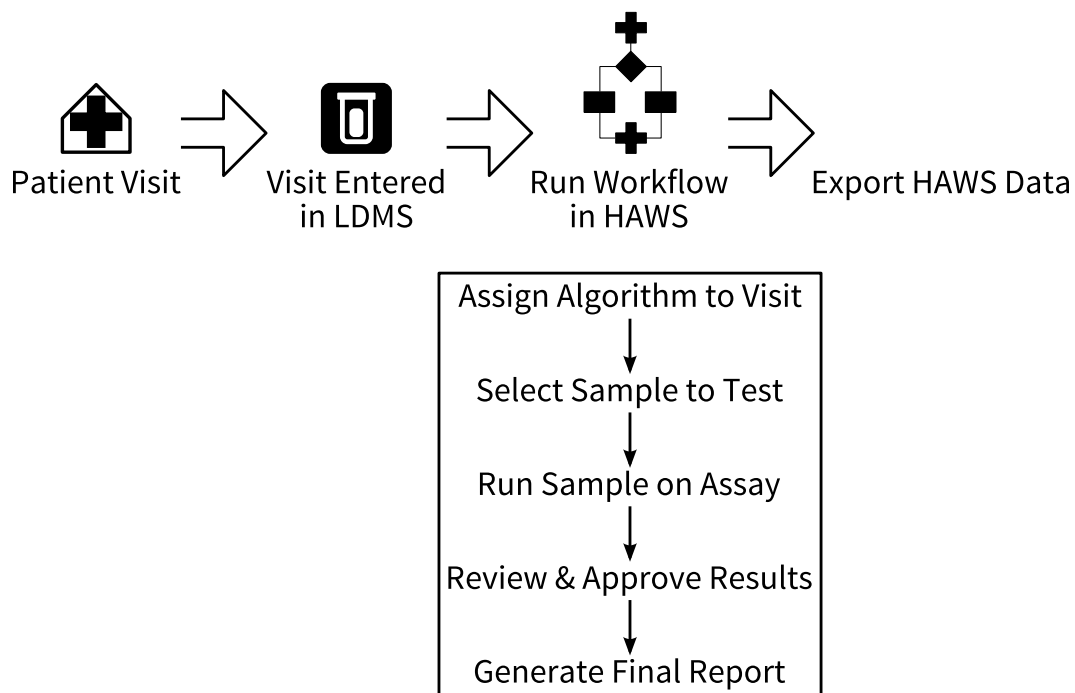
1. Verify that the file name is as expected, in the format "HAWS_Backup_ID_YYYYMMDD.bak (where "ID" is the two letter lab code).
2. Verify that the file's date of creation is as expected.
3. Verify that the file size is greater or equal to that of the previous backup file.

Tasks

HAWS works by creating *tasks* that represent each step for the visit in the algorithm.

Think of *tasks* as steps in the workflow. The tasks within workflows are shown on the left in the **Common Tasks** list. All workflows start by assigning a visit to the workflow (the *Assign a patient visit to a workflow* step), after which, they move through the remaining tasks until they are completed.

Figure 11: Basic process for a workflow in HAWS



The basic process that a patient visit will go through, with the steps that occur in HAWS emphasized

Workflows will go through the following steps:

- Assign a patient visit to a workflow** Select an algorithm for the visit, and create a new workflow for the visit using the algorithm
- Select sample** Select specimens from the visit to be tested

| | |
|-------------------------|--|
| Process assay | Add the specimens selected for testing to an assay run or create a new assay run |
| Submit redraw | Generate paperwork for submitting a request to have a specimen for a visit redrawn |
| Receive redraw | Process a specimen that has been redrawn by selecting the specimen from the new visit |
| Review assay | Review and approve the results from assay runs |
| Result algorithm | Review all the assay results for the workflow and select a final result for the workflow |
| Final report | Generate the final workflow report |

There are other steps in the **Common Tasks** list that do not fall into the sequential workflow for the steps listed above. Those non-sequential steps are:

| | |
|-------------------------------------|---|
| Manage runs | This step allows you to setup assay runs for different assays. This task happens during the <i>process assay task</i> . The reason it is separate from the sequential workflow is because specimens from different workflows could be tested on the same assay run. |
| View all workflows | This step displays all workflows that are currently in progress, and lists their current pending tasks. From here, you can view overall details about the workflow, close or cancel workflows, or perform the next task for a workflow. Think of this as a home screen so you can gauge the overall work that still needs to be completed in HAWS. |
| Reassign specimen for a test | This step allows you to change the specimen that was assigned to an assay after the <i>select sample task</i> has been completed but before the <i>process assay task</i> has been completed. You would need to do this if you wanted to use a specimen other than the one automatically selected by HAWS or if a manually selected specimen was selected in error. |

Assigning patient visits to an algorithm

Background

New workflows are created by assigning an algorithm to a patient visit. This is done using the *assign a patient visit to workflow task*.

Steps

1. Select the **Assign a patient visit to a workflow** link from the Common Tasks list on the left.

The **Assign a patient visit to workflow** window will appear.

Figure 12: The assign a patient visit to workflow task

The screenshot shows the 'Assign a patient visit to workflow' window. The sidebar on the left lists 'Common Tasks' including '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', and 'Reassign specimen for a test'. The main area has a 'Group' dropdown set to 'VTN - HIV Vaccine Trials'. Below this is the 'Optional search filters' section with fields for Patient ID, Study (996.0), Visit unit, Specimen date start/end, Received date start/end, and Import date start/end. A 'Search' button is below these filters. A table titled 'Select one or more patient visits:' displays a list of visits with columns: Patient ID, Study, Visit, Specimen date/time, Received date, Import date, Clinic, and Algorithm to start. The table contains 13 rows of visit data. At the bottom, there is a 'Start workflow' button, links for '(select all visits)' and '(deselect all visits)', and a status bar showing 'Visits found: 13' and 'Visits selected: 1'. Red circles 1-5 are overlaid on the image to highlight specific elements: 1 points to the 'Optional search filters' section, 2 points to the 'Search' button, 3 points to the 'Select one or more patient visits:' table, 4 points to the 'Algorithm to start' dropdown in the table, and 5 points to the 'Start workflow' button.

(1) filters for visit search results, (2) search for visits meeting search criteria, (3) visits that meet search criteria, (4) algorithm to use for newly created workflows, (5) create new workflow for selected visits

2. Select a group from the **Group** list.
3. Optional: Filter the search results by entering information into any of the boxes in the **Optional search filters** section.
4. Optional: Select the **Include already assigned visits** option if you want visits that have already been assigned to a workflow to appear in the search results.

This may be necessary if you need to assign an additional workflow to a visit. This might happen, for example, if a workflow for an incorrect algorithm was created for a visit.

5. Click the **Search** button.

HAWS will display a list of available patient visits found in LDMS, or patient visits that were manually created for the selected group. Rows that are highlighted indicate visits that have already been assigned to an algorithm or a visit with multiple specimen dates.

6. Select one or more visits.

To select more than one visit, hold down the Ctrl or Shift keys while selecting visits. To select all visits, click the **Select all visits** link below the search results.

7. Optional: Select an algorithm from the **Algorithm to start** list.

The default algorithm assigned by HAWS is determined by the visit units and the protocols set up in the Default Algorithms screen. If the visit unit is not one of the units listed, HAWS will not select a default algorithm.

8. Click the **Start workflow** button to set the algorithm assignments.

You cannot click the **Start workflow** button if any patient visits do not have an algorithm selected. This would only occur if a visit's visit unit was not recognized.

Related tasks

[Receive redraw task](#) on page 40

Select sample task

Automatic sample selection

When a *select sample task* is assigned to a workflow, HAWS will try to automatically select the appropriate specimen.

Using the information entered in the Storage Configuration module, HAWS will look up the *Test Now* location appropriate to the assay type. If there is one or more specimens available in the appropriate *Test Now* location(s) for the patient visit, those specimens will be selected. If there is more than one specimen available in the *Test Now* location, HAWS will use the specimen stored at the highest numbered freezer, rack, box, etc.

If there are no specimens available in the *Test Now* location(s), and there is only one specimen available in LDMS (in any storage location) for the patient visit, HAWS will select that specimen.

If more than one specimen is available you must manually select the correct specimen. Until a specimen is selected, the *select sample task* will remain pending. Additionally, it is possible to filter what samples are shown when selecting for a particular visit to show specimens marked as never store or to only include specimens from the same visit collection date.

Manually selecting samples

Background

If HAWS is not able to automatically select the correct specimen for a workflow, you will need to select the specimen manually.

Steps

1. Click the *select sample task* from the **Common Tasks** list on the left. The **Available Tasks** window will appear.
2. Select the task to which you want to manually add specimens.
3. Click the **Do task** button.

Figure 13: The Select Specimen window

| Global specimen ID | Other specimen ID | Draw date | Received date | Import date | Storage location | Primary | Additive | Derivative | Sub additive/derivative |
|--------------------|-------------------|-------------|---------------|-------------|--|---------|----------|------------|-------------------------|
| 0461-08COVF00-001 | | 18-Dec-2023 | 18-Dec-2023 | | VAZIO / 1 / 1 / BOX 1-BLD -052 / 004.003 | BLD | EDT | PL2 | N/A |
| 0461-08COVF00-002 | | 18-Dec-2023 | 18-Dec-2023 | | VAZIO / 1 / 1 / BOX 1-BLD -052 / 004.004 | BLD | EDT | PL2 | N/A |
| 0461-08COVF00-003 | | 18-Dec-2023 | 18-Dec-2023 | | VAZIO / 1 / 1 / BOX 1-BLD -052 / 004.005 | BLD | EDT | PL2 | N/A |
| 0461-08COVF00-004 | | 18-Dec-2023 | 18-Dec-2023 | | VAZIO / 1 / 1 / BOX 1-BLD -052 / 004.006 | BLD | EDT | PL2 | N/A |

The **Select Specimen** window will appear. This is where you select a specimen. The specimens for the selected patient and visit that are currently available in LDMS will be displayed.

4. Select a specimen from the list.

Related tasks

[Reassigning a specimen](#) on page 27

[Receive redraw task](#) on page 40

Reassigning a specimen

Prerequisites

The workflow must be in the *process assay task*, and no results yet entered for the specimen that is currently assigned.

You can reassign a specimen that already has a result to a task. If you do this, the specimen's existing result will be used.

Background

After completing the *select sample task*, it may be necessary to change the specimen was selected for a test. This may happen if you want to use a specimen other than one automatically selected by HAWS or if a specimen was selected in error.

Steps

1. In the **Common Tasks** list, click **Reassign specimen for a test**.
2. In the **Pending Tests** list, select the test to modify.
3. Click **Change specimen**.
4. Select a new specimen to be tested. Specimens for the visit entered into LDMS will be displayed in the **Specimens** list.
5. Click the **OK** button.

Result

The specimen assigned to the assay will be changed to the one you specified. The workflow will remain in the *process assay task* until that task is completed.

Related tasks

[Manually selecting samples](#) on page 26

Assay run management

The *manage runs task* is used to view runs that have been set up for each assay supported by HAWS. By default, only runs that have not yet been completed are displayed. Previously completed runs can be displayed by selecting the **Show completed runs** option.

Figure 14: The *manage runs task*

The screenshot shows the 'manage runs task' interface. At the top, there are two dropdown menus: 'Assay: (Any)' (callout 1) and 'Kit: (Any)' (callout 2). Below these is a table of 'Available runs' with columns 'Run ID', 'Kit', 'Date created', and 'Status'. The table contains three rows: Run ID 21 (Bio-Rad Geenius HIV 1/2 Confirmatory Assay, 01-Jun-2017, Ready for Review), Run ID 25 (Abbott Architect HIV Ag/Ab Combo, 05-Jun-2017, Ready for Review), and Run ID 27 (Abbott Architect HIV Ag/Ab Combo, 06-Jun-2017, Imported). Callout 3 points to the 'Kit' column. Below the table is a grey bar with buttons 'Edit run' (callout 4), 'Enter/review results' (callout 5), 'Cancel run', and 'New run...' (callout 6). To the right of the table are links: 'Print specimen locator' (callout 7), 'Print run worksheet', and 'Print completed run worksheet'. There is also a checkbox 'Show completed runs' and an 'Import results from file...' button.

| Run ID | Kit | Date created | Status |
|--------|--|--------------|------------------|
| 21 | Bio-Rad Geenius HIV 1/2 Confirmatory Assay | 01-Jun-2017 | Ready for Review |
| 25 | Abbott Architect HIV Ag/Ab Combo | 05-Jun-2017 | Ready for Review |
| 27 | Abbott Architect HIV Ag/Ab Combo | 06-Jun-2017 | Imported |

(1) selected assay, (2) selected kit for assay, (3) runs for the selected assay and kit, (4) change the specimens to be tested on the selected run, (5) run the assay or approve results, (6) create new run for selected assay and kit, (7) generate paperwork for selected run


The paperwork that can be printed for the assay run will vary, depending on the type of assay and its current status. The **Print specimen locator** option will be available for all assay runs.

Creating a new run

Steps

1. Select the *manage runs task* from the **Common Tasks** list on the left.
2. Select an assay from the **Assay** list.
3. Select an assay kit from the **Kit** list.
The kit options available will vary, depending on the assay selected.
4. Click the **New run...** button.
The **Setup Assay Run** window will open.
5. Select the specimen(s) to be tested from the **Available samples** list.

The available samples are all specimens assigned to this assay across all active workflows, except for algorithm-assay combinations with a different defined assay kit. To select multiple specimens, press and hold the Ctrl or Shift key.

6. Click the  button.
The selected specimen(s) will be moved to the **Selected samples** list at the bottom of the window.
7. Click the **Save run** button.

Result

The new assay run will be created and assigned a *run ID*. It will have the initial status of pending.

Related reference

[Supported assays](#) on page 7

The following assays and kits are supported by HAWS.

Assay run reports

There are several useful reports that can be generated from the *run management task*. These reports are available to the right of the **Available runs** list.

Specimen locator report

This report can be used to help locate specimens to be retrieved for testing. The report includes specimen identifiers such as the *global specimen ID* or *other specimen ID*. If the specimen was added to storage in LDMS, the report will also include the *LDMS storage location*.

Run worksheet report

This report can be generated for the Enzyme Immuno Assay (EIA), Multi-Spot Assay, OraQuick Assay, and theAlere Assay. This report can be used to assist in manually recording and entering the results of an assay run. It lists each test on the run, with blank spaces provided for you to enter the results.

Completed run worksheet report

This report can only be generated for runs that have already been entered. It can be used to assist in the verification and approval of results for each test on the run. It is similar to the Run Worksheet Report, except that it includes the test results that were entered.

Running an assay

Steps

1. Open the *manage runs task*.
2. Select an assay from the **Assays** list.
To display all pending assay, runs, select (Any) from the **Assay** list.

3. Select a kit from the **Kit** list.
To display runs for all kits for the selected assay, select (Any) from the **Kit** list.
4. Select an assay run from the **Available runs** list.
If you do not see an assay run, you may need to create it.
5. Click the **Enter/review results** button.

The **Assay Results** window for the assay appears. This window contains information about the run and specimens being tested. The **Samples** list contains a listing of specimens being tested on the run. These specimens are in the same order as they would appear on the Specimen Locator Report, Run Worksheet Report, and Completed Run Worksheet Report.

Figure 15: The Assay Results window

The screenshot shows the 'Assay Results' window with the following elements and numbered callouts:

- 1**: A list of specimens being tested, currently showing 'HDK0F536-02'.
- 2**: Patient ID: 287400203, Visit: 2.1 Exp, Draw date: 29-May-2017.
- 3**: Final result: HIV Negative.
- 4**: Entered by: F. Sales (FS), Entered date: 01-Jun-2017, and a 'Commit results' button.
- 5**: Approved by: I. Georg (IG), Approved date: 01-Jun-2017, and a 'De-approve results' button.
- 6**: Assay-specific fields including gp36, gp140, p31, gp160, p24, gp41, and HIV-1/HIV-2 interpretations.
- 7**: A 'Close' button at the bottom right of the window.

(1) specimens being tested, (2) details for selected specimen, (3) final result for the assay run, (4) finalize results for selected specimen, (5) approve committed results, (6) fields specific to the assay being run will appear here, (7) save changes and close the window

The **Samples** list shows the following information:





Note: If you only see the specimen identifier for specimens being tested, click **View > Extra test info in assay results** from the HAWS menu bar.

| | |
|-------------------|---|
| specimen | This is the identifier for the specimen, such as the <i>global specimen ID</i> |
| Patient ID | This is the patient identifier for the specimen |
| Wf ID | This is the workflow ID for the workflow to which the specimen is assigned. |
| T | Indicates whether or not the specimen has been tested. Y indicates that the specimen has been tested; N indicates that the specimen has not been tested. |
| R | Indicates whether or not the specimen has had its result committed in HAWS. Y indicates that the specimen result has been committed; N indicates that the specimen has not yet been tested. |
| A | Indicates whether or not the specimen's result has been reviewed and approved. Y indicates that the result has been approved; N indicates that the specimen has not yet been approved. |

6. Optional: To change the status of the run to Assigned, select the **Assigned to technician for testing** option.
If you select this option, you can click the **Close** button to exit the **Assay Results** window. The status of the assay run will be updated to reflect that it has been assigned.
7. Select a specimen from the **Samples** list on the left.
8. Optional: If you do not want to include this test's results in the final report for the workflow, select the **Do not report** option.
9. Optional: If you do not want to include this assay test's results in the export file that is generated to be sent to SCHARP, select the **Do not export to SCHARP** option.
10. Enter the assay results in the fields on the right.
The result fields will vary, depending on the assay you are running. Refer to the appropriate section for the assay you are running for more information.
11. After the results for each specimen have been entered, click the **Commit results** button.

Committing results indicates that you are finished entering results for the assay.

 **Important:** Committing results immediately advances the workflow to the *review assay task* if all tests for the current step in the workflow are completed.

 **Note:** If you attempt to modify results after they have been committed, you will be prompted with a warning, but will still be permitted to change the result. Runs that have been approved cannot be modified unless they are de-approved.

- 12.** Click the **Close** button.
Changes made to the assay run will automatically be saved. If you want to close the window without saving changes, select the **X** button in the upper-right corner of the window.

Result

At this point, the assay has been run, however the results have not been approved.

Related tasks

[Export reports](#) on page 52

Export reports are tab-delimited text files that are intended to be sent to SCHARP.

Available Results for Assay Types

Abbott Prism assay

The valid options for the specimen **Final result** are:

- Reactive
- Nonreactive
- Equivocal
- QNS
- Invalid
- Test Not Performed

Bio-Rad Geenius HIV 1/2 Confirmatory Assay

The valid options for the specimen **Final result** are:

- HIV Negative
- HIV-2 Indeterminate
- HIV-1 Indeterminate
- HIV Indeterminate
- HIV-1 Positive
- HIV-2 Positive
- HIV-2 Positive (with HIV-1 Cross-reactivity)
- HIV Positive Untypable
- QNS
- Invalid
- Test Not Performed
- Inconclusive

Results can be entered for the following bands, with plus or minus available for each band:

- gp36
- gp140
- p31
- gp160

- p24
- gp41
- Ctrl

Results can be entered for HIV-1 Interpretation and HIV-2 Interpretation, and the result options for those are the following:

- Reactive
- Non-reactive
- Indeterminate



Note: HAWS will only permit a test result to be committed or approved if none of the detailed result fields are unspecified, unless the result is invalid, QNS, or test not performed.

HAWS will only permit a test result to be committed or approved if none of the bands are unspecified, unless the result is invalid, QNS, or test not performed. HAWS will also calculate the expected result, and warn you if the result selected does not match the expected result.

Alere assay

There are three result fields that must be completed for this assay:

- control
- HIV-1 p24 Ag
- HIV-1/2 Ab

For each band, select either `reactive` or `non-reactive`. These boxes must be completed, unless the final result is QNS, Invalid, or Test Not Performed.

The valid options for the final test result are:

- Non-reactive
- Reactive for HIV Antibody
- Reactive for HIV Antigen
- Reactive for HIV Antibody and Antigen
- QNS
- Invalid
- Test Not Performed

DNA PCR assay

The valid options for the final test result are:

- Detected
- Not Detected
- Equivocal
- QNS
- Invalid
- Test Not Performed

Enzyme Immuno Assay (EIA)

The following result fields are specific to the EIA assay:

| | |
|------------------------|--|
| Final result | <p>HAWS will automatically complete this field for you based on the OD/cutoff ratio. You can override the automatically calculated result if needed. The following options are available for the EIA final result:</p> <ul style="list-style-type: none">• Reactive• Non-reactive• Equivocal (only available for the Bio-Rad GenScreen HIV 1/2 and Bio-Rad Genscreen Ultra HIV Ag-Ab HIV 1/2 kits)• QNS• Invalid• Test Not Performed |
| Qualifier | <p>This is the operand for the OD. By default, this field is set to =. If the reader device detected an OD outside of its range of quantitation, you would need to change this to reflect the range.</p> |
| OD | <p>The OD result for the specimen. The default value is blank. You must enter a non-negative number unless the Final Result field is <i>Invalid, QNS, or Test Not Performed</i>.</p> |
| Cutoff | <p>The cutoff result for the specimen. The default value is blank. You must enter a non-negative number unless the Final Result field is <i>Invalid, QNS, or Test Not Performed</i>.</p> |
| OD/cutoff ratio | <p>This read-only value is automatically calculated based on the OD and Cutoff that you entered for the specimen.</p> |
| S/CO | <p>This field is displayed instead of OD and cutoff for the Abbott Architect HIV Ag/Ab Combo and Abbott AxSYM HIV Ag/Ab Combo kits. The default value is blank. You must enter a non-negative number unless the Final Result field is <i>Invalid, QNS, or Test Not Performed</i>.</p> |

HAWS will complete the **Final result** field for you using the logic described below. You can override the result chosen by HAWS and select a different result. If the ID/cutoff ratio is modified, HAWS may modify the **Final result**, but will provide you with a message if it does.

For all EIA kits other than the Bio-Rad GenScreen HIV 1/2 and Bio-Rad Genscreen Ultra HIV Ag-Ab HIV 1/2 kits, HAWS will suggest a **final result** using the following logic:

- Ratio greater than or equal to 1.0 will be considered *Reactive*
- Ratio less than 1.0 will be considered *Non-reactive*

For the Bio-Rad GenScreen HIV 1/2 and Bio-Rad Genscreen Ultra HIV Ag-Ab HIV 1/2 kits, the following logic applies:

- Ratio greater than or equal to 1.0 will be considered *Reactive*

- Ratio between 0.90 and 0.99, inclusive, will be considered Equivocal
- Ratio less than 0.90 will be considered Non-reactive

HIV-1 Total Nucleic Acid Assay

The valid options for the specimen **Final result** are:

- HIV-1 Nucleic Acid Detected
- HIV-1 Nucleic Acid Not Detected
- Inconclusive
- Indeterminate
- Invalid
- QNS
- Test Not Performed

Multi-Spot assay

The following result fields must be completed for each Multi-Spot assay specimen:

- Control
- HIV-1 Peptide
- HIV-1 Recombinant
- HIV-2 Peptide

The valid options for each of these fields are `Reactive` or `Non-reactive` (or `null` if the `Final result` for the specimen is `Invalid`, `QNS`, or `Test Not Performed`).

The valid options for the `Final result` are:

- Non-reactive
- Reactive, HIV-1
- Reactive, HIV-2
- Reactive, HIV-1/2
- Invalid
- QNS
- Test Not Performed

Open discretionary assay

The open discretionary assay is not part of any workflows. It can only be assigned as a discretionary assay. It is intended for scenarios when the laboratory needs to provide results for a discretionary assay not already defined in HAWS.

You must provide the following information about the assay.

| Field | Options |
|--------------|--|
| Final Result | HIV-1 Antibody Reactive/Positive HIV-1 Antibody Non-reactive/Negative HIV-2 Antibody Reactive/Positive HIV-2 Antibody Non-reactive/Negative HIV Antibody Reactive/Positive HIV Antibody Non-reactive/Negative HIV-1 Antigen Reactive/Detected HIV-1 Antigen Non-reactive/Not Detected HIV Antibody and Antigen Reactive/Detected HIV Antibody and Antigen Non-reactive/Not Detected Reactive/Positive/Detected Non-reactive/Negative/Not Detected HIV-1 Nucleic Acid Detected HIV-1 Nucleic Acid Not Detected HIV-2 Nucleic Acid Detected HIV-2 Nucleic Acid Not Detected Equivocal QNS Invalid Inhibited Inconclusive Indeterminate Non-specific Test Not Performed Other |
| Assay Name | Enter the name of the assay |
| 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) Other |

Related tasks

[Adding a discretionary test to a workflow](#) on page 44

RNA PCR assay

There are two result fields that must be completed for this assay:

qualifier This is the operand for the **Copies/mL**. By default, this field is set to =. If the reader device detected copies

outside of its range of quantification, you would need to change this to reflect the range.

copies/mL

Must be a non-negative integer. Can only be left blank if the **Final result** for the specimen is *Invalid, Inhibited, QNS, or Test Not Performed*.

The valid options for the final test result are:

- HIV-1 RNA Detected
- Not Detected
- QNS
- Invalid
- Inhibited
- Detected Below Limit of Quantitation
- Detected Above Limit of Quantitation
- Test Not Performed

Western Blot assays

The Western Blot assays have result fields for each blot band. All blot band fields will be blank by default. You must select a result for each blot band unless the **Final result** is *Invalid, QNS, or Test Not Performed*.

The following are valid options for the **Final result** field for Western Blot assays:

- Positive
- Negative
- Indeterminate
- QNS
- Invalid
- Non-Specific
- Test Not Performed

Approving assay runs**Prerequisites**

Note: To approve results, you must have the *user can approve results* permission for your account.

Background

After assay results have been committed by a user entering or importing them, they must be verified.

Steps

1. Open the *Manage runs task*.
2. Select the assay run that you want to approve.
3. Click the **Enter/review results** button.

The **Assay Results** window will open.

4. Select a specimen from the **Samples** list on the left.
The results for the selected sample will be displayed on the right.
These are the results you are reviewing.
5. Click the **Approve results** button.
The specimen results will be approved and the **Approve results** button will change to **De-approve results**.
6. Repeat for each specimen in the **Samples** list.
7. After all specimens have been approved, click the **Close** button.

Result

The assay run is now considered reviewed and approved. If the run had a final result of *Invalid*, the results will not be used by HAWS but the results will be included in the export file (unless the option to exclude the results from the export file was enabled).

Once the result has been approved it cannot be modified. If an approved result needs to be modified, you must first **De-approve** the result

Associating assay results from another workflow

For assays common to multiple algorithms, HAWS allows you to transfer the results for the same time point from the assay on one workflow to another workflow.

To use the results of a previously run assay, click the **Use Selected Test** button. If manually completing the *Process Assay task* is needed, click the **Don't use an existing test** button.

Importing assay results from a file

Prerequisites

You can import results from an assay reader device for some assay kits. Results can be imported from the following kits:

- Bio-Rad Genetic Systems HIV 1/2 Plus O
- Bio-Rad GS HIV Combo Ag/Ab EIA
- Bio-Rad Genetic Systems rLav
- Bio-Rad Geenius HIV 1/2 Confirmation Assay
- Abbott Architect HIV Ag/Ab Combo

Background

Importing assay results from a file allows you to bypass entering the results manually.

Steps

1. Open the *manage runs task*.

2. Select the appropriate run from the **Available runs** list.
3. Click the **Import results from file** button.
A dialog window will open for you to browse to the file to be imported.
4. Select the file that you want to import.

Result

HAWS will extract all results from the file, and any existing results will be overwritten.

HAWS will extract the appropriate test data for each sample on the run.

Submit redraw task


Background

Certain combinations of results may cause a redraw task to be assigned for a workflow. The exact circumstances will vary, depending on the algorithm.

To initiate a redraw request for a specimen:

Steps

1. Select the *submit redraw task* from the **Common Tasks** list.
2. Select the workflow for which you want to process a redraw request.
3. Click the **Do task** button.
4. Optional: Change the default text in the **Summary** box.
 - 4.1. Click the **Select text...** button.
 - 4.2. Select a new template from the **Redraw reason** list.
 - 4.3. Click the **OK** button.
 - 4.4. Update the text in the **Summary** box.
5. Click the **Print redraw report** button.
The Blinded HIV-1 Infection Status Report will open in the SAP Crystal Reports® Report Viewer.
6. Required: Click the **[Print]** icon from the Report Viewer toolbar.

 **Important:** You must print the Blinded HIV-1 Infection Status Report. The workflow will not move on to the *receive redraw task* until the report has been printed.

Result

After the Blinded HIV-1 Infection Status Report has been printed, the workflow will be moved to the *receive redraw task*.

Related tasks

[Adding a discretionary redraw to a workflow](#) on page 45

Receive redraw task

Background

The *receive redraw task* is for workflows that have completed the *submit redraw task*. After the redraw has occurred, you need to associate the new visit as a redraw visit for the patient. To do this:

Steps

1. Open the *receive redraw task* from the **Common Tasks** list on the left.
2. Select the workflow for which you have a redrawn specimen.
3. Click the **Do task** button.
The **Select Redraw Visit** window will open. This window is similar to the *assign a patient visit to a workflow task*. Only visits for the patient with specimens that have a *specimen date* on or after the date of the original specimen being redrawn will be displayed.
4. Select the visit with the redrawn specimen.
 - If the visit was entered in LDMS, it will be listed in the **Select Redraw Visit** window.
 - If the visit was not entered in LDMS, click the **New visit** button to create it.
5. Click the **OK** button.

Result

The workflow will be moved to the *select sample task*, and you can now test specimens from the redraw visit. You can continue to process the workflow as normal.



Note: the workflow will only create a *select sample task* if the algorithm triggers tests after a redraw and will not be the case after a discretionary redraw. If this is the case, the user must create discretionary tests on their own.

Related tasks

[Manually selecting samples](#) on page 26

[Assigning patient visits to an algorithm](#) on page 24

Result algorithm task

Prerequisites




Note: To complete the *result algorithm task*, you must have the **user can approve results** permission.

Background

The *result algorithm task* is used to review and assign a final result to a workflow. After all specimen testing work has been completed for a workflow, the workflow will be assigned to the result algorithm task. This is where you will review the results for specimens tested and select the final result for the workflow.

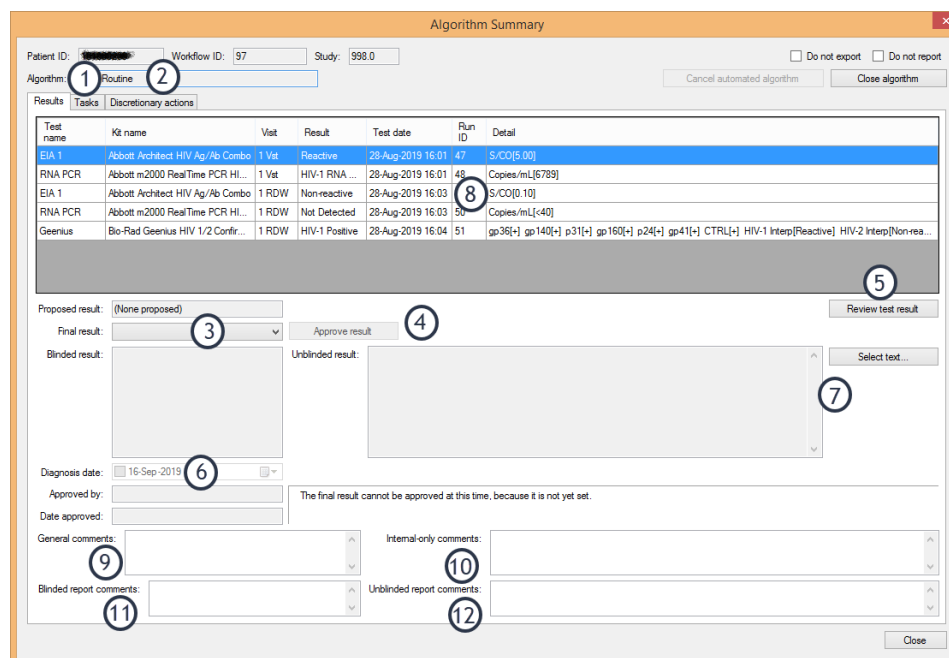
Steps

1. Open the *result algorithm task*.
2. Select the workflow for which you want to complete the *result algorithm task*.

 **Note:** If you do not see the workflow available, go to the *view all workflows task* and ensure that all other necessary tasks have been completed.
3. Click the **Do task** button.

The **Algorithm Summary** window () will open.

Figure 16: The Algorithm Summary window




The screenshot shows the 'Algorithm Summary' window. At the top, there are fields for Patient ID, Workflow ID (97), and Study (998.0). Below these are tabs for 'Results' and 'Discretionary actions'. A table lists test results with columns: Test name, Kit name, Visit, Result, Test date, Run ID, and Detail. The table contains five rows of data. Below the table, there are sections for 'Proposed result', 'Final result', 'Blinded result', and 'Unblinded result'. There are also fields for 'Diagnosis date', 'Approved by', 'Date approved', 'General comments', 'Internal-only comments', 'Blinded report comments', and 'Unblinded report comments'. Numbered callouts (1-12) point to various elements: (1) Algorithm dropdown, (2) Workflow ID field, (3) Final result dropdown, (4) Approve result button, (5) Review test result button, (6) Diagnosis date field, (7) Unblinded result text area, (8) Detail column in the table, (9) General comments text area, (10) Internal-only comments text area, (11) Blinded report comments text area, and (12) Unblinded report comments text area.

| Test name | Kit name | Visit | Result | Test date | Run ID | Detail |
|-----------|----------------------------------|-------|----------------|-------------------|--------|--|
| EIA 1 | Abbott Architect HIV Ag/Ab Combo | 1 Vet | Reactive | 28-Aug-2019 16:01 | 47 | S/CO[5.00] |
| RNA PCR | Abbott m2000 RealTime PCR HI... | 1 Vet | HIV-1 RNA ... | 28-Aug-2019 16:01 | 48 | Copies/mL[6789] |
| EIA 1 | Abbott Architect HIV Ag/Ab Combo | 1 RDW | Non-reactive | 28-Aug-2019 16:03 | 49 | S/CO[0.10] |
| RNA PCR | Abbott m2000 RealTime PCR HI... | 1 RDW | Not Detected | 28-Aug-2019 16:03 | 50 | Copies/mL[<40] |
| Genieus | Bio-Rad Genieus HIV 1/2 Confr... | 1 RDW | HIV-1 Positive | 28-Aug-2019 16:04 | 51 | gp36[+] gp140[+] p31[+] gp160[+] p24[+] gp41[+] CTRL[+] HIV-1 Interp[Reactive] HIV-2 Interp[Non-res... |

(1) view tasks that were completed for the workflow, (2) view and create discretionary tests and redraw tasks, (3) final result for the workflow, (4) approve workflow final result, (5) review the results for the selected test, (6) date infection was diagnosed for positive results only, (7) summary comments as will appear on unblinded reports, (8) tested completed for the workflow, (9) general comments that appear on HIV status report, (10) internal-only comments that are not exported or shown on reports, (11) blinded report comments that show only on the blinded report, (12) unblinded report comments that only show on the unblinded report

4. Review all of the test results.

- 4.1. Select a test on the **Results** tab.
 - 4.2. Click the **Review test result** button.
 - 4.3. Click the **Close** button when you are finished reviewing.
5. Select a final result for the workflow from the **Final result** list.
The **Proposed result** field provides a suggested **Final result** that was determined by HAWS.
6. If the **Final result** is *Infected*, specify a **Diagnosis date**
This is only required if there are infected specimens from multiple dates. If the infected specimen is from one date, HAWS will automatically select it for you. For protocols that require adjudication, you will not be able to complete the **Diagnosis date** until the Adjudication Report is generated. This is done by clicking the **Report to Adjudicator** button that will appear next to the **Diagnosis date**.
7. For algorithms that have an unblinded result, select the **Unblinded result [summary text]**.
The following algorithms have an unblinded result:
 - Evaluation of Sero-Reactivity
 - Evaluation of Sero-Reactivity Recent Exposure
 - Post-Study
 - Post-Study Testing Service
 - Confirmation Testing Service
 - Follow-Up Testing ServiceHAWS will automatically select text for you. You can select a different summary text template by clicking the **Select text...** button.
8. Enter comments into the following **Comment** text boxes:
 - General comments: the text you enter here will appear on the HIV status final report
 - Internal-only comments: the text you enter here will not be exported or appear on reports
 - Blinded report comments: The text you enter here will show only on the blinded report
 - Unblinded report comments: the text you enter here will show only on the unblinded report

 **Note:** If you change the **Final result** for a workflow for which a final workflow report has already been printed, you must enter a comment to explain why the result was changed.
9. Click the **Approve result** button.
10. Click the **Close** button.

Result

The completed workflow will be assigned the *final report task*.

Related tasks

[Cancelling an algorithm for a workflow](#) on page 47

Final report task

Background

After a workflow has completed the *result algorithm task*, it will be assigned the *final report task*. For this task, you will generate the final workflow report.



Tip: You can print the final reports for several workflows at once from the *Reports* menu.

Steps

1. Open the *final report task*.
2. Select the workflow for which you will be generating a report.
3. Click the **Do task** button.
The SAP Crystal Reports® **Report Viewer** window will open with the HIV Infection Status Report.
4. Click the **Print** button from the **Report Viewer** toolbar.



Note: The *final report task* for the workflow will not be completed until the report is printed.

Related tasks

[Batch printing final reports](#) on page 50

Workflow management

View all workflows

The *view all workflows task* allows you to see all active (and inactive) workflow on one screen, as well as each workflow's currently assigned task.

Figure 17: The *view all workflows task*

| Patient ID | Workflow ID | Workflow name | Study | Visit | Specimen date | Completed at | Algorithm start date | Pending task |
|------------|-------------|---------------|-------|-------|---------------|--------------|----------------------|---------------|
| 287400418 | 83 | Routine AMP | 704.0 | 2 Vst | 01-Jun-2017 | 06-Jun-2017 | | Process Assay |

(1) filter workflows that are displayed, (2) next task to be completed for the workflow, (3) workflows meeting filter criteria, (4) view or approve selected workflow, (5) generate (or re-generate) final workflow report, (6) add a new discretionary test to the selected workflow, (7) add a new discretionary redraw to the selected workflow, (8) complete the next task for the selected workflow

Almost all of your work in HAWS can be completed from this screen. It is also very useful for keeping track of open workflows. From this screen you can do the following:

- Execute the next task in a workflow
- Review previous tasks, assay run results, and the HIV Infection Status Report
- Add discretionary tests and discretionary redraws
- Modify the export status of a workflow.

Discretionary tests and redraws

Adding a discretionary test to a workflow

Background

In addition to the tests automatically generated by HAWS, you can add discretionary tests to any active workflow.³ Discretionary tests are processed just like tests assigned by an algorithm. The workflow will be assigned the *select sample task* and *process assay task* to complete the discretionary test.

The results from discretionary tests will appear in the **Algorithm Summary** window with other test results and will appear on the workflow's final report. Discretionary tests will also be exported to SCHARP (unless explicitly excluded

³ You cannot add discretionary tests to workflows using the Infected or Retrospective algorithms.

by the user). Discretionary tests will *not* be used, however, in the automated determination of a proposed final algorithm result.

Steps

1. Open the *view all workflows task*.
2. Select the workflow for which you want to add a discretionary test.
3. Click the **Add discretionary test...** button.
The **Start Discretionary Test** window will open.
4. Select an assay from the **Available assay types** list.
5. Optional: Modify the **Assay name** box.
6. Click the **OK** button.

Result

The discretionary test will now be added to the workflow and can be completed like any other assay in a workflow. You can see what discretionary tests have been assigned to a workflow on the **Algorithm Summary** window, accessed by selecting the workflow in the *view all workflows task*, and then clicking the **Details** button.

Related concepts

[Open discretionary assay](#) on page 35

Adding a discretionary redraw to a workflow

Background

A discretionary redraw allows you to manually add a *submit redraw task* to a workflow. This can be done for the following algorithms:

- Routine (VST) (and Routine Vaccine or mAb)
- Evaluation of Sero-Reactivity (EOS)
- Evaluation of Sero-Reactivity Recent Exposure (EOX)
- Post-Study (POS)
- Recent Exposure/Acute Infection (EXP) (and Recent Exposure/Acute Infection Vaccine or mAb)

After a new visit has been selected, it becomes the current visit for the workflow, provided that it is the most recent visit. Any new discretionary tests and *select sample task*s will be associated with the redraw visit.

Redraw visits will be included on the workflow's final report.

Filter by: Patient ID: ☐ Include completed and terminated workflows

Workflows: Pending task:

| Patient ID | Workflow ID | Workflow name | Study | Visit | Specimen date | Completed at | Algorithm start date | Pending task |
|------------|-------------|-------------------------------|-------|-------|---------------|--------------|----------------------|--------------|
| 287400418 | 83 | Routine AMP | 704.0 | 2 Vst | 01-Jun-2017 | | 06-Jun-2017 | Report |
| 101000247 | 85 | Evaluation of Sero-Reactivity | 998.0 | 5 Vst | 04-May-2009 | | 15-Aug-2019 | SelectSample |

Start Discretionary Redraw ✕

The following redraw reasons are available for the selected algorithm ("Routine AMP"). Please select the reason to be used for the initial text of the redraw request. (This text can be edited when submitting the redraw request.)

Redraw reason

<None> - Reason text will initially be blank.


Further Testing Required. Draw new sample per protocol requirements and submit using visit type "Redraw/RDW".

Further Testing Required. Draw a new 10 mL EDTA whole blood sample using visit type "Redraw/RDW". Ship the whole blood tube (unprocessed) overnight, ambient, to the HDTL.

☒ Automatically add EIA, RNA PCR, and Geenius tests after redraw is received

Steps

1. Open the *view all workflows task*.
2. Select the workflow for which you want to add a discretionary visit from the **Workflows** list.
3. Click the **Add discretionary redraw...** button.

 **Note:** If the **Add discretionary redraw...** button is disabled, the workflow may have an algorithm that does not allow discretionary visits.

The **Start Discretionary Redraw** window will open.

4. Select the desired reason for requesting the redraw the from the **Redraw reason** list.

The redraw reasons available will vary, depending on the workflow's algorithm. You will be able to change the text of the redraw reason prior to generating the redraw request report.
5. Check the box at the bottom of the window if automatically adding EIA, RNA PCR, and Geenius tests after the redraw is received is needed.
6. Click the **OK** button.

Result

The workflow will be assigned a *submit redraw task*. Complete the *submit redraw task* as normal.

Related tasks

[Submit redraw task](#) on page 39

Cancelling discretionary tests and redraws

Background

Discretionary tests and redraws can be removed from a workflow if they should not be completed or were added in error.

Steps

1. Open the *view all workflows task*.
2. Select the workflow for which you want to remove a discretionary visit or redraw.
3. Click the **Details...** button.
The **Algorithm Summary** window appears.
4. Change to the **Discretionary actions tab**.
This tab shows all discretionary tests and discretionary redraws that have been added to a workflow.
5. Select the discretionary test or redraw to be removed.
6. Click the **Delete** button.

Cancelling an algorithm for a workflow

Background

Cancelling an algorithm for a workflow means that you want to depart from the normal steps in the workflow's algorithm. You will still be able to perform discretionary tests and redraws. You will also still be able to set the final result for the workflow and complete the *final report task*.

Cancelling an algorithm differs from *closing a workflow*. Cancelling an algorithm interrupts the algorithm for the workflow, but still allows you to generate a final report for the workflow. Closing a workflow ends the workflow without the option to generate a final report.

Steps

1. Open the *view all workflows task*.
2. Select the workflow you want to cancel from the **Workflows** list.
3. Click the **Details** button.
The **Algorithm Summary** window will appear.
4. Click the **Cancel automated algorithm** button.
You will be asked to confirm that you want to end the algorithm for the selected workflow.

Result

Any discretionary tests or redraws assigned to the workflow must still be completed. Once there are no pending discretionary tasks, the cancelled workflow will be assigned the *result algorithm workflow task*.


Related tasks

[Result algorithm task](#) on page 40

Closing a workflow

Background

You can close any workflow that has not completed the *result algorithm task*. You may need to close a workflow because it was created in error or because it was created using the wrong algorithm. Closing a workflow will cancel any pending tasks for the algorithm (discretionary tasks will remain). You will not be permitted to set a final result or print a final workflow report.

 **Warning:** Closing a workflow will automatically apply the **Do Not Export** and **Do Not Report** options to the workflow.

Steps

1. Open the *view all workflows task*.
2. Select the workflow that you want to close from the **Workflows** list. The **Algorithm Summary** window will open.
3. Click the **Close algorithm** button.

Available reports

HAWS has several reports that are useful for managing your laboratory's workflows and productivity.

To generate these reports, click **Reports** > **[Report name]** from the HAWS menu bar. For some reports, you may be asked to supply some information prior to generating the report, such as a date range.

The following reports are available:

Crashed Workflows

The Crashed Workflows report lists which workflows have crashed. The user may use this to verify if a new workflow was initiated as a replacement.

Pending algorithms

The Pending algorithms report shows all workflow tasks that are in progress and not yet completed. Tasks are grouped by workflow.

Pending redraw samples

The Pending redraw samples report lists all pending *receive redraw tasks* (that is, specimens for which a *submit redraw task* has been completed and the report printed).

| | | | | | |
|---|---|---------------------------------------|--|--------------------------------------|---|
| Protocol/visit type summary | The Protocol/visit type summary report lists the workflows that have been started or completed for each patient. | | | | |
| Tests per algorithm | The Tests per algorithm report lists the number of runs for assay kits. The report is grouped by both kit and by algorithm, and distinguishes between initial visits and redraws. | | | | |
| Turn around time >= X days | The Turn around time >= X days report shows workflows with a turn around time of greater than or equal to X days, where X is a number of days specified by the user. | | | | |
| Turn around time details | View turn around time details. | | | | |
| Turn around time non-exported | The Turn around time non-exported report shows workflows that have not yet been exported. | | | | |
| Turn around time summary | <p>The Turn around time summary report shows the turn around time difference in days from each event to the next event for each workflow. Weekend days are excluded from the calculation as well as any holidays that were entered within Holiday Administration. The Turn Around Time Summary Report is broken down into percentile ranks. Each rank ignores a certain percentage of the events for that workflow to show the average and maximum for the remainder. The following percentages are included:</p> <table><tr><td>average/ maximum (100)</td><td>Shows the averages and maximums for all events</td></tr><tr><td>average/ maximum (95)</td><td>Shows the averages and maximums with the bottom 5% (slowest) events of each type excluded</td></tr></table> | average/ maximum (100) | Shows the averages and maximums for all events | average/ maximum (95) | Shows the averages and maximums with the bottom 5% (slowest) events of each type excluded |
| average/ maximum (100) | Shows the averages and maximums for all events | | | | |
| average/ maximum (95) | Shows the averages and maximums with the bottom 5% (slowest) events of each type excluded | | | | |
| Turn around time with redraws only | The Turn around time with redraws only report shows workflows that included at least one redraw. | | | | |
| Visits per algorithm | The Visits per algorithm report lists the number of visits for algorithms within a date range specified by the user. The report distinguishes between initial visits and redraws. | | | | |

Batch printing final reports

Prerequisites



Note: Only users with the **Can print reports** privilege can batch print reports.

Background

HAWS can print the final reports for multiple workflows at once. This feature can be used to save time by printing multiple reports at once. The reports will be saved automatically in PDF format and printed without needing to open SAP Crystal Reports® Report Viewer.



Warning: Using this feature will automatically print the selected reports to your default printer. If you need to specify the printer to use, you must change the default printer in your Windows® Control Panel.

Steps

1. Click **Reports > Batch-print reports...** from the HAWS menu bar. The **Print Reports** window will open.
2. Optional: If you want to print reports that have already been printed, select the **Include already created reports** option.
3. Select the report(s) to print.
To select multiple reports, hold down the Ctrl or Shift key.
4. Optional: Click the **Print list**.
This will display a list of the reports that will be printed. You can print this list for review, if needed.
5. Click the **Print reports** button.

Result

The reports will be printed from your computer's default printer. PDF files for each report will also be generated and saved to your computer. They will be in the `Reports` folders. There will be a directory in the `Reports` folder for each clinic. Within each clinic's folder will be the PDF report.

The default location for reports can be modified in the **Options** window.

Related concepts

[Options window](#) on page 11

Related tasks

[Final report task](#) on page 43

Creating unblinded EOS/EOX reports

Prerequisites



Note: Only users with the **Can print reports** privilege can batch print reports.

Background

Prior to a protocol being unblinded, SCHARP receives unblinded EOS/EOX reports. SCHARP will request that the laboratory send unblinded EOS/EOX reports for all patients on a specific protocol, or they may send the laboratory a text file containing a list of patients whose unblinded EOS/EOX reports should be sent.

Steps

1. Click **Reports > Create unblinded EOS reports for SCHARP** from the HAWS menu bar.
The **Create Unblinded Reports for SCHARP** window will appear.
2. Do one of the following:
 - If SCHARP provided your laboratory with a protocol number, enter the protocol into the **Create reports for all algorithms for this protocol** box.
 - If SCHARP provided your laboratory with a text file listing of patients, click the **Open file** button and select the text file.
3. Optional: If you want to print reports that have already been printed, select the **Include already created reports** option.
4. Select the reports to be printed.
To select multiple reports, hold down the Ctrl or Shift key.
5. Click the **Create reports** button.

Result

PDF files for each report will be generated and saved to your computer. They will be in the **Reports** folders. There will be a sub-directory in the **Reports** folder called **Unblinding**. Within this directory will be a directory for each clinic, and within each clinic's folder a PDF of the report.

Figure 18: Unblinding report directory structure

```
C:\fstrf-haws\Reports\Unblinding\[protocol]\[clinic]\[report].pdf
```

Figure 19: Report PDF file naming convention

```
[PatientID]-v[Visit Number]-[Draw Date]-  
rpt[Algorithm]Unblinded.pdf  
123456789-v7-24Aug-2009-rptEvaluationofSeroReactivityUnblinded.pdf
```

The default location for reports can be modified in the **Options** window.

Related concepts

[Options window](#) on page 11

Export reports

Export reports are tab-delimited text files that are intended to be sent to SCHARP.

Background

An export file is generated for each protocol and contains test results for all completed workflows. Results for sub-studies are included in the same export file as the parent protocol.

Only test results from completed workflows are included in export files. Results from protocols marked as locked will not be exported, nor will individual tests or workflows that have been marked as **Do not export**.



Note: Western Blot tests using the Bio-Rad New Lav Blot II kit will not be included in export files.

Steps

1. On the **File** menu, click **Export Results**.
2. When the "Export Results" message appears, click **OK**.

After you are finished

The export files will be placed in the export base folder.



Note: If any export files were generated again, their filename will be appended with a number.

Related concepts

[Options window](#) on page 11

Related tasks

[Running an assay](#) on page 29

Generating adjudication report

Steps

1. In the tasks list, click **View all workflows**.
2. In the Workflows list, select the workflow for which you will be generating the adjudication report.
3. Click **Details**.
4. (If required), select the result from the **Final Result** box.
5. In the **Diagnosis** box, select the date of the diagnosis.

6. Click **Report to adjudicator**.

Result

The adjudication report will be in the Adjudication folder in the export directory.

Related tasks

[Changing protocol adjudication settings](#) on page 13

Algorithms

This section lists details about the various algorithms that are available in HAWS.

Confirmation Algorithm (visit = CFM)

Figure 20: Confirmation algorithm

Confirmation

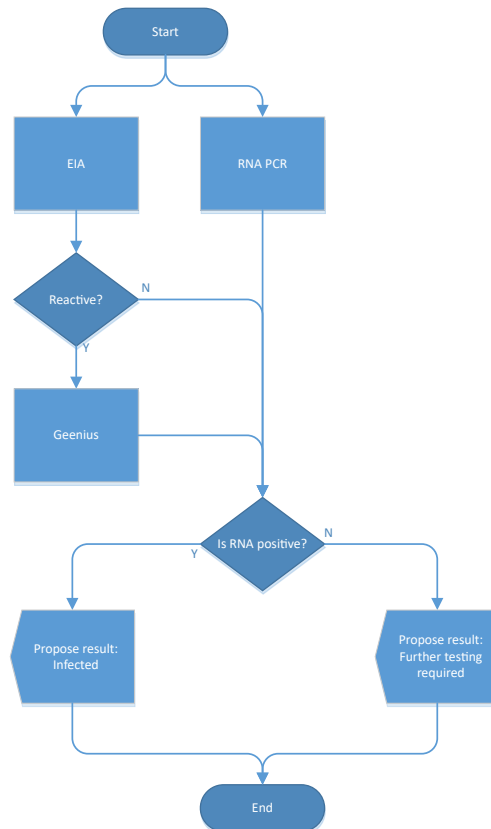


Table 1: CFM Algorithm - Blinded and Unblinded Report Summary Comments

| | ECR (EIA/ CMIA/ Rapid) | Geenius (assay interpretation) | HIV-1 RNA | HIV-1 TNA | HIV-2 RNA | HIV-2 TNA | Unblinded CFM result summary text |
|----|---------------------------------------|---|----------------------|----------------------|----------------------|----------------------|---|
| 1 | Non-reactive x3 | Not required | Not detected | Not detected | Not required | Not required | Further testing required. Draw a new 10mL EDTA whole blood sample using visit type "Follow-up" (FUP). |
| 2 | Reactive x1 or 2 or 3 | Negative | Not detected | Not detected | Not required | Not required | Further testing required. Draw a new 10mL EDTA whole blood sample using visit type "Follow-up" (FUP). |
| 3 | Reactive x1 or 2 or 3 | HIV1 indeterminate or HIV1 positive | Not detected | Not detected | Not required | Not required | Further testing required. Draw a new 10mL EDTA whole blood sample using visit type "Follow-up" (FUP). |
| 4 | Reactive x1 or 2 or 3 | Negative, or HIV1 indeterminate, or HIV1 positive | Detected | Not required | Not required | Not required | HIV-1 Infected |
| 5 | Reactive x1 or 2 or 3 | Negative, or HIV1 indeterminate, or HIV1 positive | Not detected | Detected | Not required | Not required | HIV-1 Infected |
| 6 | Reactive x1 or 2 or 3 | HIV2 Positive | Not detected | Not required | Not required | Not required | HIV-2 Infected |
| 7 | Reactive x1 or 2 or 3 | HIV Positive-Untypable | Not detected | Not detected | Detected | Not detected | HIV-2 Infected |
| 8 | Reactive x1 or 2 or 3 | HIV Positive-Untypable | Not detected | Not detected | Not detected | Detected | HIV-2 Infected |
| 9 | Reactive x1 or 2 or 3 | HIV Positive-Untypable | Detected | Not required | Detected | Not required | HIV-1 and HIV-2 Infected |
| 10 | Reactive x1 or 2 or 3 | HIV Positive-Untypable | Not detected | Detected | Not detected | Detected | HIV-1 and HIV-2 Infected |

HVTN EOS Algorithm (visit = EOS)

Figure 21: HVTN EOS algorithm

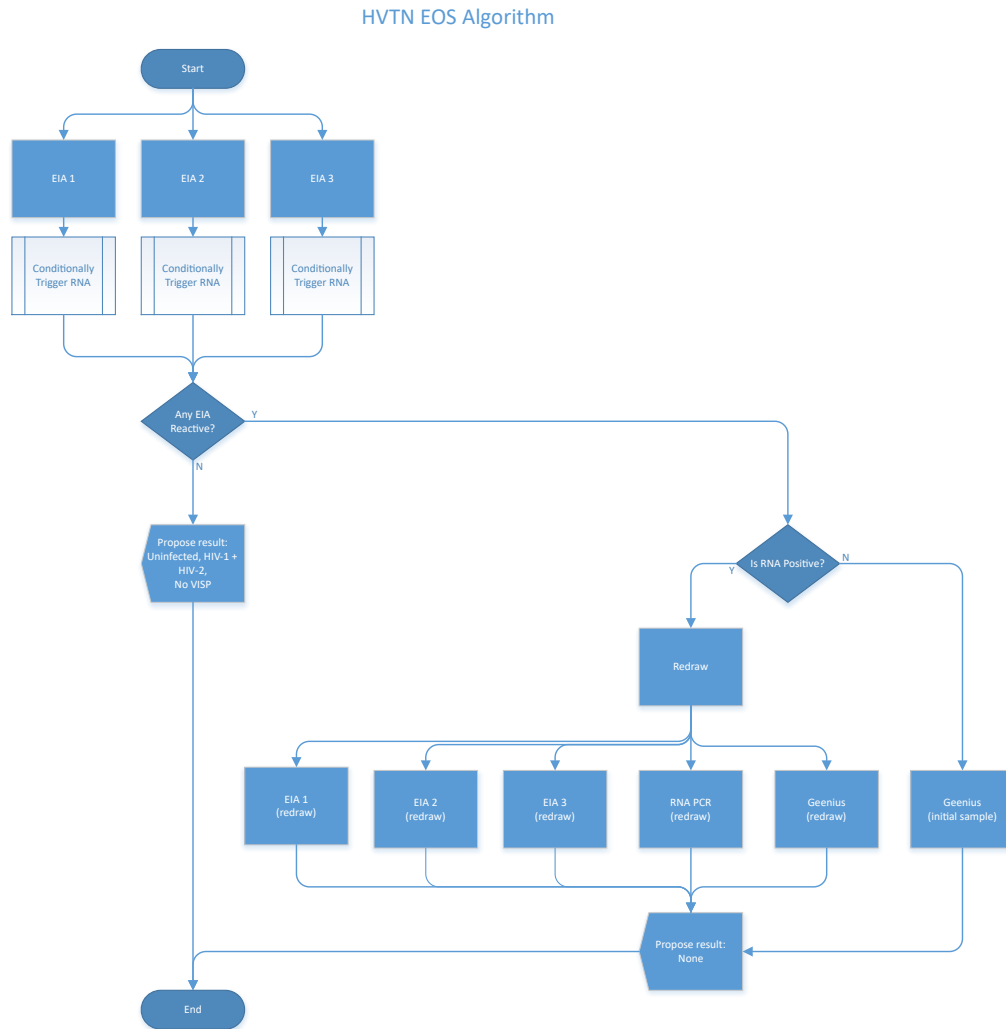


Table 2: EOS Algorithm – Blinded and Unblinded Report Summary Comments

| | ECR (EIA/ CMIA/ Rapid) | Geenius (assay interpretation) | HIV-1 RNA | HIV-1 TNA(or DNA) | HIV-2 RNA | HIV-2 TNA | Unblinded EOS result summary text |
|---|---|---|----------------------|----------------------------------|----------------------|----------------------|--|
| 1 | Non-reactive x3 + NR Abbott Prism | Not required | Not required | Not required | Not required | Not required | No evidence of infection with HIV-1 or HIV-2. No evidence of vaccine-induced sero-reactivity or serological cross-reactivity. |
| 2 | Non-reactive x3 + Reactive Abbott Prism | Not required | Not required | Not required | Not required | Not required | No evidence of infection with HIV-1 or HIV-2. No evidence of non-specific sero-reactivity or vaccine-induced sero-reactivity (if participant received vaccine product) by most recent methods available. Evidence of non-specific or possible vaccine-induced sero-reactivity by a less specific method (Abbott Prism HIV-1/2/O Plus). |
| 3 | Reactive x1 or 2 or 3 | Negative | Not Detected | Not Detected | Not required | Not required | 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. |
| 4 | Reactive x1 or 2 or 3 | HIV1 indeterminate or HIV1 positive (consistent with product) | Not Detected | Not Detected | Not required | Not required | 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. |

| | ECR (EIA/ CMIA/ Rapid) | Geenius (assay interpretation) | HIV-1 RNA | HIV-1 TNA(or DNA) | HIV-2 RNA | HIV-2 TNA | Unblinded EOS result summary text |
|----|---|--|----------------------|----------------------------------|----------------------|----------------------|---|
| 5 | Reactive x1 or 2 or 3 | Negative or HIV1 indeterminate or HIV1 positive or HIV Positive, Untypable | Detected | Not required | Not required | Not required | Infected, HIV-1 |
| 6 | Reactive x1 or 2 or 3 | Negative or HIV-1 indeterminate or HIV-1 positive or HIV Positive, Untypable | Not detected | Detected | Not required | Not required | Infected, HIV-1 |
| 7 | Reactive x1 or 2 or 3 | HIV2 Positive | Not required | Not required | Not required | Not required | Infected, HIV-2 |
| 8 | Reactive x1 or 2 or 3 | HIV2 indeterminate | Not required | Not required | Detected | Not required | Infected, HIV-2 |
| 9 | Reactive x1 or 2 or 3 | HIV2 indeterminate | Not required | Not required | Not detected | Detected | Infected, HIV-2 |
| 10 | Reactive x1 or 2 or 3 | HIV Positive, Untypable | Not detected | Not detected | Detected | Not detected | Infected, HIV-2 |
| 11 | Reactive x1 or 2 or 3 | HIV Positive, Untypable | Not detected | Not detected | Not detected | Detected | Infected, HIV-2 |
| 12 | Reactive x1 or 2 or 3 | HIV Positive, Untypable | Detected | Not required | Detected | Not required | Infected, HIV-1 and HIV-2 |
| 13 | Reactive x1 or 2 or 3 | HIV Positive, Untypable | Not detected | Detected | Not detected | Detected | Infected, HIV-1 and HIV-2 |
| 14 | Reactive x1 or 2 or 3 | HIV Positive, Untypable | Detected | Not required | Not detected | Detected | Infected, HIV-1 and HIV-2 |
| 15 | Non- reactive x2 + Antigen reactive Abbott Determine | Negative | Not Detected | Not required | Not required | Not required | No evidence of infection with HIV-1/2 and no evidence of vaccine-induced seropositivity/ reactivity (VISP/R). These results (antigen reactivity with non- detectable RNA results) are consistent with non-specific cross-reactivity (false reactive, not VISP/R). |

Evaluation of Sero-Reactivity Recent Exposure Algorithm (visit = EOX)

Figure 22: Evaluation of Sero-Reactivity Recent Exposure (EOX) algorithm

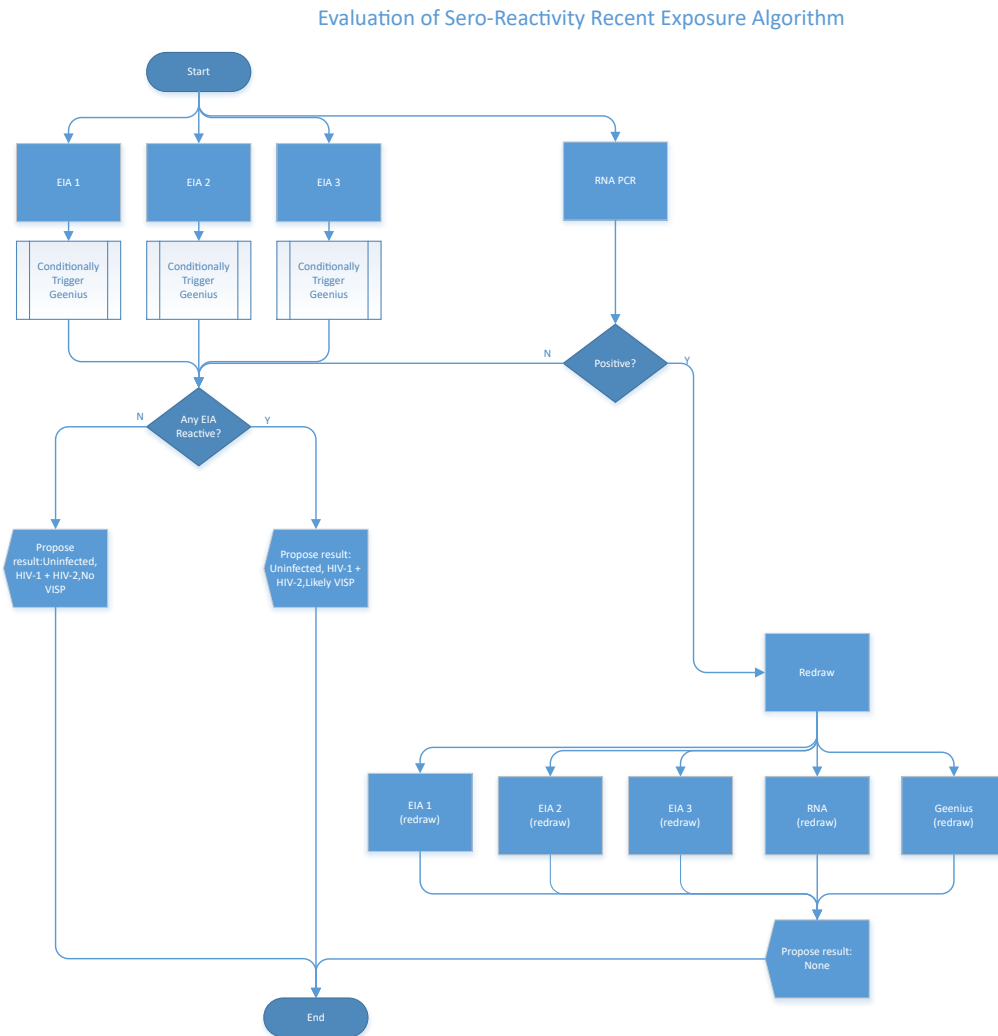


Table 3: EOX Algorithm – Blinded and Unblinded Report Summary Comments

| | ECR (EIA/CMIA/Rapid) | Geenius (assay interpretation) | HIV-1 RNA | HIV-1 TNA (or DNA) | HIV-2 RNA | HIV-2 TNA | Unblinded EOX result summary text |
|---|---|--------------------------------|--------------|--------------------|--------------|--------------|--|
| 1 | Non-reactive x3 + NR Abbott Prism | Not required | Not detected | Not required | Not required | Not required | No evidence of infection with HIV-1 or HIV-2. No evidence of vaccine-induced sero-reactivity or non-specific serological cross-reactivity. If any previous HVTN HIV diagnostic test results showed evidence of vaccine-induced sero-reactivity, it is recommended that HIV diagnostic testing continue through the HVTN until no evidence of sero-reactivity is repeatedly demonstrated. |
| 2 | Non-reactive x3 + Reactive Abbott Prism | Not required | Not detected | Not required | Not required | Not required | No evidence of infection with HIV-1 or HIV-2. No evidence of non-specific sero-reactivity or vaccine-induced sero-reactivity (if participant received vaccine product) by most recent methods available. Evidence of non-specific or possible vaccine-induced sero-reactivity by a less specific method (Abbott Prism HIV-1/2/O Plus). |
| 3 | Reactive x1 or 2 or 3 | Negative | Not Detected | Not detected | Not required | Not required | 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. |

| | ECR (EIA/ CMIA/ Rapid) | Geenius (assay interpretati | HIV-1 RNA | HIV-1 TNA (or DNA) | HIV-2 RNA | HIV-2 TNA | Unblinded EOX result summary text |
|-----|------------------------------|---|-----------------|-----------------------------|-----------------|-----------------|---|
| 4 | Reactive x1 or 2 or 3 | HIV1 indeterminate or HIV1 positive (consistent with product) | Not Detected | Not detected | Not required | Not required | 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. |
| 5 | Reactive x1 or 2 or 3 | Negative or HIV1 indeterminate or HIV1 positive or HIV Positive, Untypable | Detected | Not required | Not required | Not required | Infected, HIV-1 |
| 6 | Reactive x1 or 2 or 3 | Negative or HIV-1 indeterminate or HIV-1 positive or HIV Positive, Untypable | Not detected | Detected | Not required | Not required | Infected, HIV-1 |
| 7a | Reactive x1 or 2 or 3 | HIV2 Positive | Not detected | Not required | Detected | Not required | Infected, HIV-2 |
| 7b | Reactive x1 or 2 or 3 | HIV2 Positive | Not detected | Not required | Not detected | Detected | Infected, HIV-2 |
| 8a | Reactive x1 or 2 or 3 | HIV2 indeterminate | Not detected | Not required | Detected | Not required | Infected, HIV-2 |
| 8b | Reactive x1 or 2 or 3 | HIV2 indeterminate | Not detected | Not required | Not detected | Detected | Infected, HIV-2 |
| 9a | Reactive x1 or 2 or 3 | HIV Positive, Untypable | Not detected | Not detected | Detected | Not detected | Infected, HIV-2 |
| 9b | Reactive x1 or 2 or 3 | HIV Positive, Untypable | Not detected | Not detected | Not detected | Detected | Infected, HIV-2 |
| 10a | Reactive x1 or 2 or 3 | HIV Positive, Untypable | Detected | Not required | Detected | Not required | Infected, HIV-1 and HIV-2 |

| | ECR (EIA/ CMIA/ Rapid) | Geenius (assay interpretati | HIV-1 RNA | HIV-1 TNA (or DNA) | HIV-2 RNA | HIV-2 TNA | Unblinded EOX result summary text |
|-----|---|--|----------------------|---------------------------------------|----------------------|----------------------|--|
| 10b | Reactive x1 or 2 or 3 | HIV Positive, Untypable | Not detected | Detected | Not detected | Detected | Infected, HIV-1 and HIV-2 |
| 11 | Non- reactive x2 + Antigen reactive Abbott Determine | Negative | Not Detected | Not required | Not required | Not required | No evidence of infection with HIV-1/2 and no evidence of vaccine- induced seropositivity/ reactivity (VISP/R). These results (antigen reactivity with non-detectable RNA results) are consistent with non-specific cross- reactivity (false reactive, not VISP/R). |

Vaccine Recent Exposure Algorithm (visit = EXP)

Figure 23: Vaccine Recent Exposure Algorithm

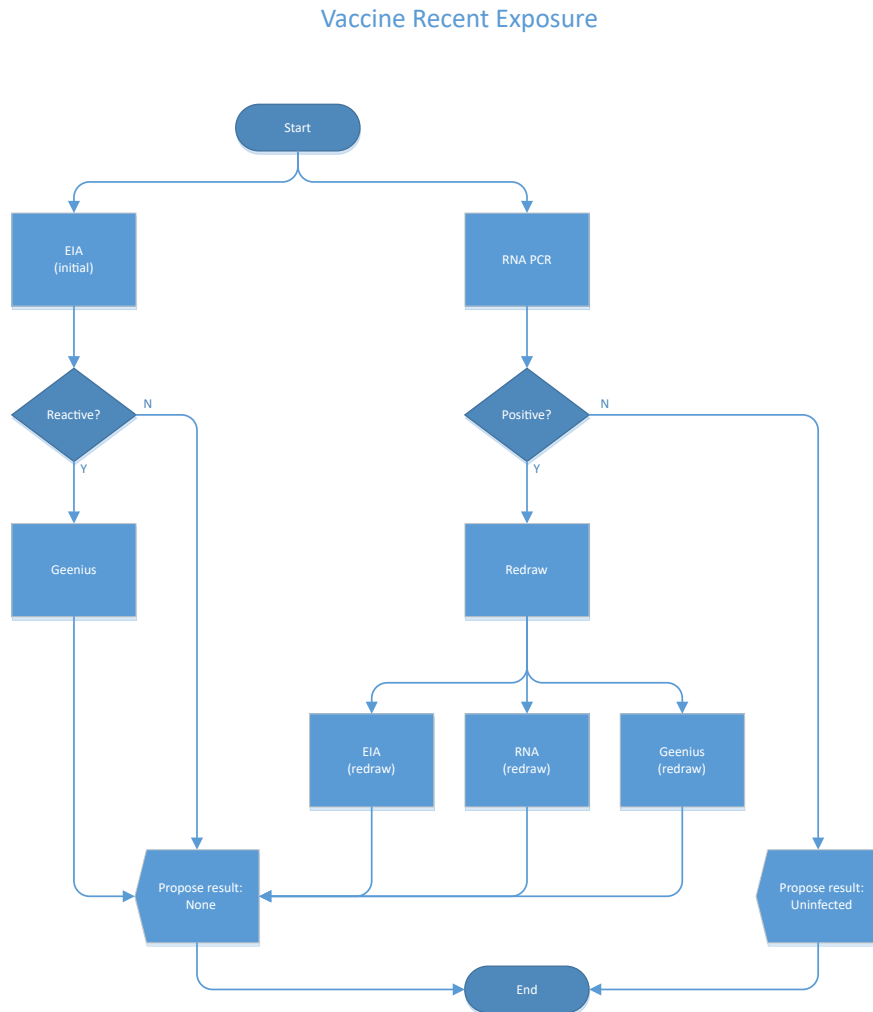
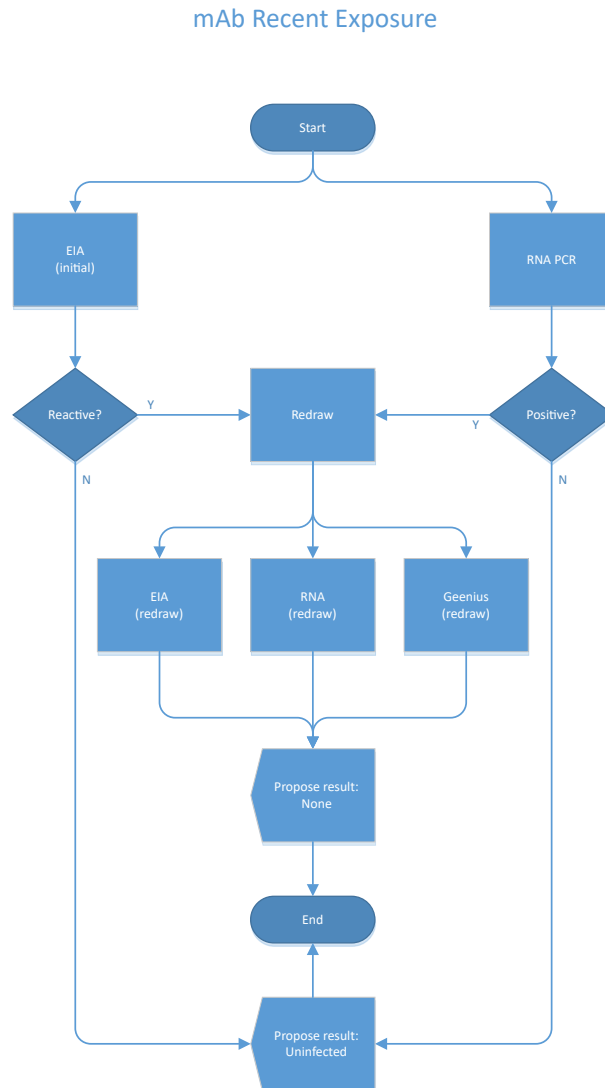


Table 4: EXP Algorithm - Unblinded Report Summary Comments

| ECR (EIA/CMIA/ Rapid) | HIV-1 RNA | Geenius | HIV-1 TNA (or DNA) | Unblinded EXP result summary text |
|----------------------------------|------------------|-----------------|-----------------------------------|---|
| Non-reactive x1 ECR | Not detected | Not required | Not required | No evidence of infection with HIV-1 or HIV-2. |
| Non-reactive x1 ECR | Not detected | Any | Not required | No evidence of infection with HIV-1 or HIV-2. |
| Reactive or Equivocal x1 ECR | Not detected | Not required | Not required | No evidence of infection with HIV-1 or HIV-2. These results may indicate vaccine-induced sero- reactivity, or these results may be due to non-specific serological cross-reactivity. No further testing is required at this time. Vaccine- induced sero-reactivity will be confirmed at the end of the study. |
| Reactive or Equivocal x1 ECR | Not detected | Any | Not required | No evidence of infection with HIV-1 or HIV-2. These results may indicate vaccine-induced sero- reactivity, or these results may be due to non-specific serological cross-reactivity. No further testing is required at this time. Vaccine- induced sero-reactivity will be confirmed at the end of the study. |
| Reactive or Equivocal x1 ECR | Detected | Any | Not required | HIV-1 Infected |

mAb Recent Exposure Algorithm (visit = EXP)

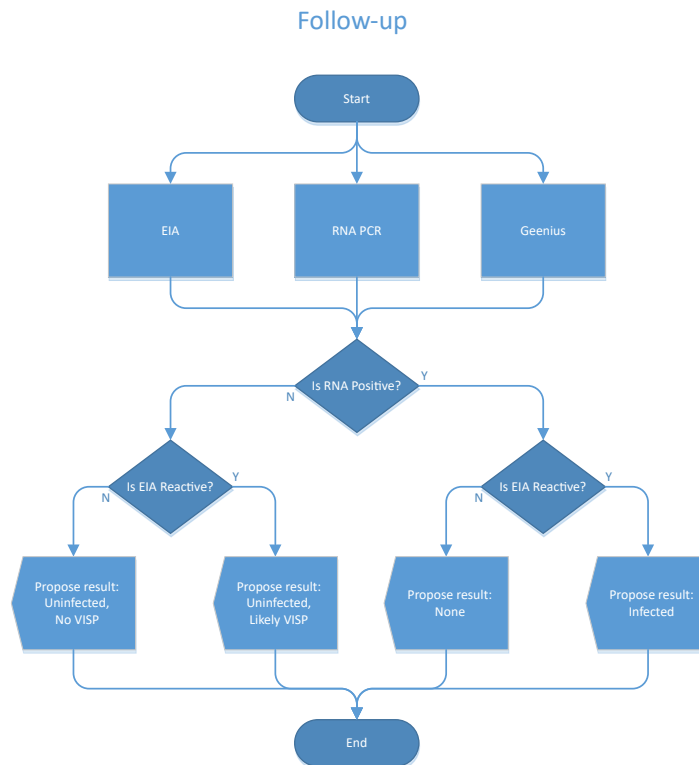
Figure 24: mAb Recent Exposure Algorithm



| ECR Criteria | RNA Criteria | Geenius Criteria | Pass | Proposed Algorithm Result Summary |
|------------------------------|------------------------------|-------------------------|-------------|--|
| Non-reactive x1 ECR | Non-reactive x1 ECR | N/A | 1 | No evidence of infection with HIV-1 or HIV-2. |
| Reactive or Equivocal 1x ECR | Any | Any | 1 | Further Testing Required. Draw new sample per protocol requirements and submit using visit type Redraw/RDW |
| Any | Reactive or Equivocal 1x ECR | Any | 1 | Further Testing Required. Draw new sample per protocol requirements and submit using visit type Redraw/RDW |

Follow-up Algorithm (visit = FUP)

Figure 25: Follow-up algorithm

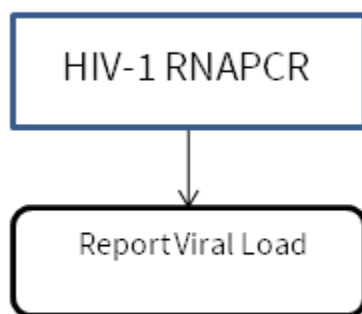


| ECR Criteria | HIV-1 RNA Criteria | HIV-1 DNA Criteria | Pass | Proposed Algorithm Result Summary |
|------------------|--------------------|--------------------|------|--|
| Non-reactive x 1 | Not detected | Not detected | 1 | Blinded: No evidence of infection with HIV-1. Unblinded Report: No evidence of infection with HIV-1. If any previous HVTN HIV diagnostic test results showed evidence of vaccine-induced sero-reactivity, it is recommended that HIV diagnostic testing continue through the HVTN until no evidence of sero-reactivity is repeatedly demonstrated. |
| Reactive x1 | Not detected | Not detected | 1 | Blinded: No evidence of infection with HIV-1. Unblinded: No evidence of infection with HIV-1. These results may be due to vaccine-induced sero-reactivity (VISR) or non-specific cross-reactivity. |
| Reactive x1 | Not detected | Positive | 1 | Blinded or Unblinded: HIV-1 Infected based on FUP and SRV or CFM lab results. |
| Reactive x1 | Positive | Positive | 1 | Blinded or Unblinded: HIV-1 Infected based on FUP and SRV or CFM lab results. |

Infected Testing Algorithm (visit = INF)

Figure 26: Infected testing algorithm

Algorithm used for infected protocols or infected tracks within a protocol



Note: Report to include testing lab code and VL kit name/code

Post-study Algorithm (visit = POS)

Figure 27: Post-study (POS) algorithm

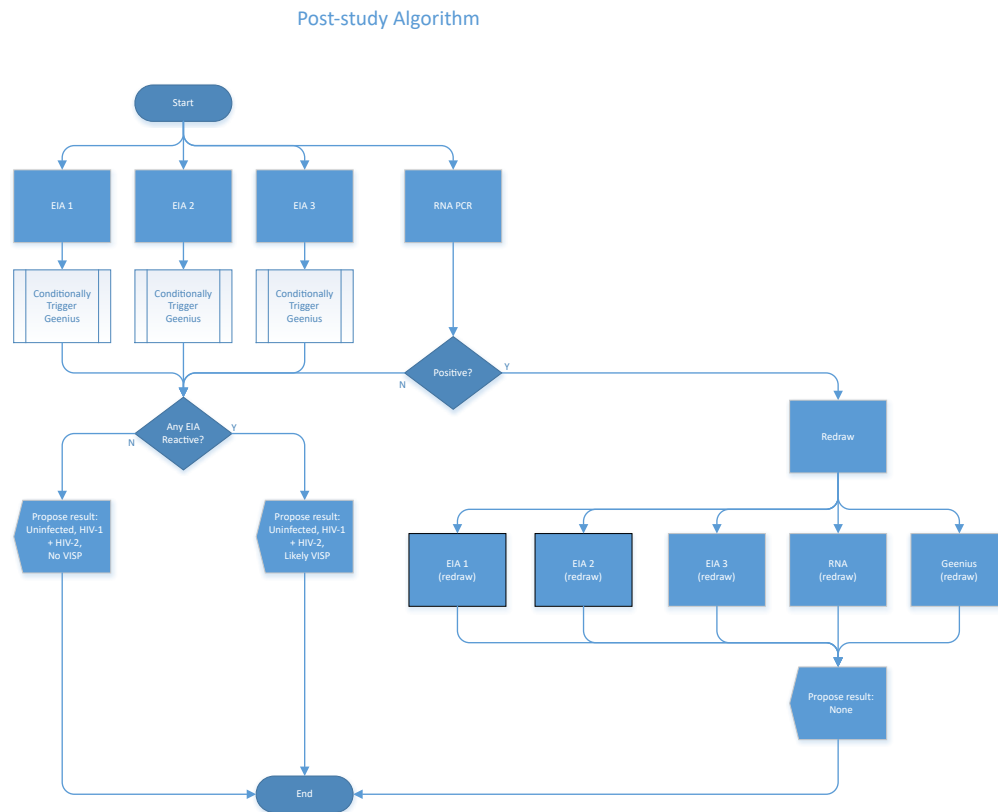


Table 5: POS Algorithm – Blinded and Unblinded Report Summary Comments

| | ECR (EIA/CMIA/Rapid) | Geenius (assay interpretation) | HIV-1 RNA | HIV-1 TNA (or DNA) | HIV-2 RNA | HIV-2 TNA | Unblinded POS result summary text |
|---|---|--------------------------------|--------------|--------------------|--------------|--------------|--|
| 1 | Non-reactive x3 + NR Abbott Prism | Not required | Not detected | Not required | Not required | Not required | No evidence of infection with HIV-1 or HIV-2. No evidence of vaccine-induced sero-reactivity or non-specific serological cross-reactivity. If any previous HVTN HIV diagnostic test results showed evidence of vaccine-induced sero-reactivity, it is recommended that HIV diagnostic testing continue through the HVTN until no evidence of sero-reactivity is repeatedly demonstrated. |
| 2 | Non-reactive x3 + Reactive Abbott Prism | Not required | Not detected | Not required | Not required | Not required | No evidence of infection with HIV-1 or HIV-2. No evidence of non-specific sero-reactivity or vaccine-induced sero-reactivity (if participant received vaccine product) by most recent methods available. Evidence of non-specific or possible vaccine-induced sero-reactivity by a less specific method (Abbott Prism HIV-1/2/O Plus). |
| 3 | Reactive x1 or 2 or 3 | Negative | Not Detected | Not detected | Not required | Not required | 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. |

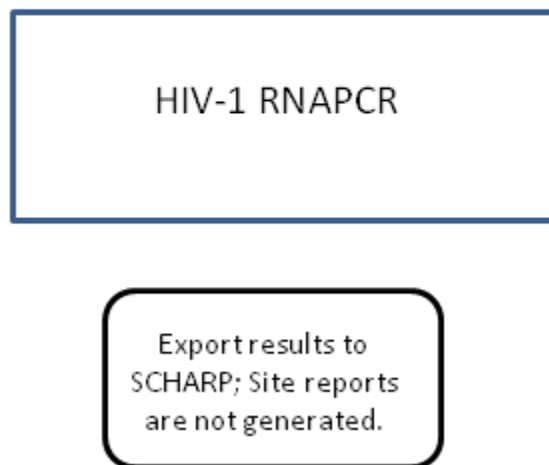
| | ECR (EIA/ CMIA/ Rapid) | Geenius (assay interpretati | HIV-1 RNA | HIV-1 TNA (or DNA) | HIV-2 RNA | HIV-2 TNA | Unblinded POS result summary text |
|-----|------------------------------|---|-----------------|-----------------------------|-----------------|-----------------|---|
| 4 | Reactive x1 or 2 or 3 | HIV1 indeterminate or HIV1 positive (consistent with product) | Not Detected | Not detected | Not required | Not required | 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. |
| 5 | Reactive x1 or 2 or 3 | Negative or HIV1 indeterminate or HIV1 positive or HIV Positive, Untypable | Detected | Not required | Not required | Not required | Infected, HIV-1 |
| 6 | Reactive x1 or 2 or 3 | Negative or HIV-1 indeterminate or HIV-1 positive or HIV Positive, Untypable | Not detected | Detected | Not required | Not required | Infected, HIV-1 |
| 7a | Reactive x1 or 2 or 3 | HIV2 Positive | Not detected | Not required | Detected | Not required | Infected, HIV-2 |
| 7b | Reactive x1 or 2 or 3 | HIV2 Positive | Not detected | Not required | Not detected | Detected | Infected, HIV-2 |
| 8a | Reactive x1 or 2 or 3 | HIV2 indeterminate | Not detected | Not required | Detected | Not required | Infected, HIV-2 |
| 8b | Reactive x1 or 2 or 3 | HIV2 indeterminate | Not detected | Not required | Not detected | Detected | Infected, HIV-2 |
| 9a | Reactive x1 or 2 or 3 | HIV Positive, Untypable | Not detected | Not detected | Detected | Not detected | Infected, HIV-2 |
| 9b | Reactive x1 or 2 or 3 | HIV Positive, Untypable | Not detected | Not detected | Not detected | Detected | Infected, HIV-2 |
| 10a | Reactive x1 or 2 or 3 | HIV Positive, Untypable | Detected | Not required | Detected | Not required | Infected, HIV-1 and HIV-2 |

| | ECR (EIA/ CMIA/ Rapid) | Geenius (assay interpretati | HIV-1 RNA | HIV-1 TNA (or DNA) | HIV-2 RNA | HIV-2 TNA | Unblinded POS result summary text |
|-----|---|-----------------------------------|-----------------|-----------------------------|-----------------|-----------------|--|
| 10b | Reactive x1 or 2 or 3 | HIV Positive, Untypable | Not detected | Detected | Not detected | Detected | Infected, HIV-1 and HIV-2 |
| 11 | Non- reactive x2 + Antigen reactive Abbott Determine | Negative | Not Detected | Not required | Not required | Not required | No evidence of infection with HIV-1/2 and no evidence of vaccine- induced seropositivity/ reactivity (VISP/R). These results (antigen reactivity with non-detectable RNA results) are consistent with non-specific cross- reactivity (false reactive, not VISP/R). |

Retrospective Algorithm (visit = RRV)

Figure 28: Retrospective (RRV) algorithm

Internal algorithm used for retrospective viral load testing if required by the protocol. Viral loads will be ordered on previous visit specimens until a "RNA Not Detected" result is obtained. Results are not reported to clinic.



Post-study Testing Service Algorithm (visit = SRV)

Figure 29: Post study testing service (SRV) algorithm

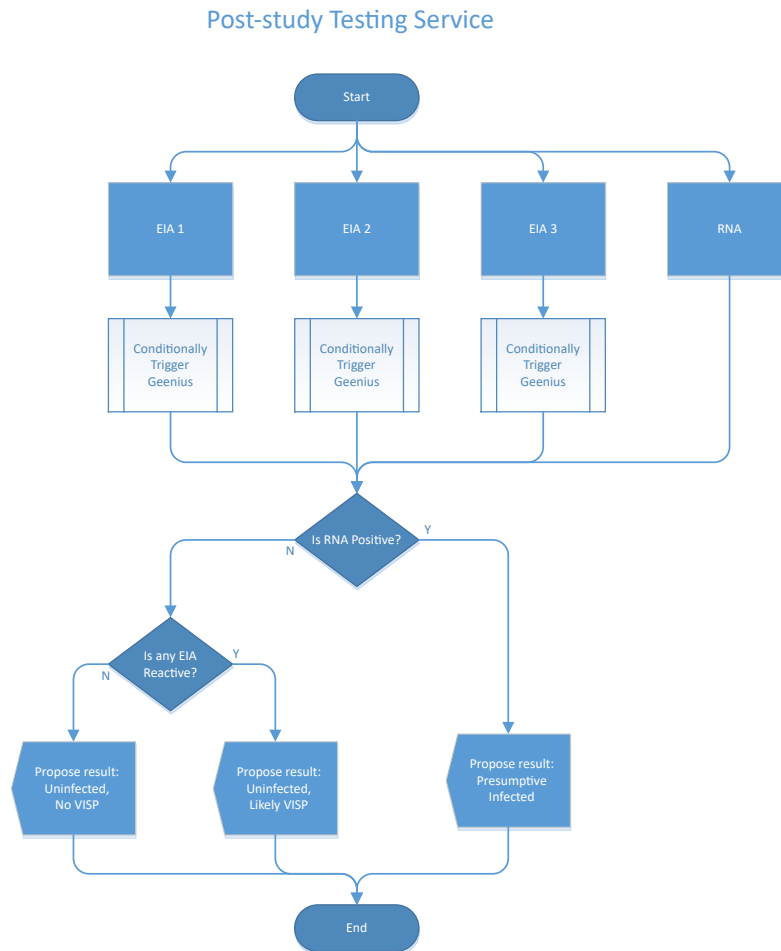


Table 6: SRV Algorithm - Blinded and Unblinded Report Summary Comments

| | ECR (EIA/ CMIA/ Rapid) | Geenius (assay interpretati | HIV-1 RNA | HIV-1 TNA (or DNA) | HIV-2 RNA | HIV-2 TNA | Unblinded SRV result summary text |
|-------------------|--|-----------------------------------|-----------------|-----------------------------|-----------------|-----------------|--|
| 1 | Non- reactive x3 + NR Abbott Prism | Not required | Not detected | Not required | Not required | Not required | No evidence of infection with HIV-1 or HIV-2. No evidence of vaccine-induced sero-reactivity or non-specific serological cross-reactivity. If any previous HVTN HIV diagnostic test results showed evidence of vaccine-induced sero-reactivity, it is recommended that HIV diagnostic testing continue through the HVTN until no evidence of sero-reactivity is repeatedly demonstrated. |
| 2 | Non- reactive x3 + Reactive Abbott Prism | Not required | Not detected | Not required | Not required | Not required | No evidence of infection with HIV-1 or HIV-2. No evidence of non-specific sero-reactivity or vaccine-induced sero-reactivity (if participant received vaccine product) by most recent methods available. Evidence of non-specific or possible vaccine-induced sero-reactivity by a less specific method (Abbott Prism HIV-1/2/O Plus). |
| 3a PrEP yes | Reactive x1 or 2 or 3 | Negative | Not Detected | Not detected | Not required | Not required | 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. |

| | ECR (EIA/ CMIA/ Rapid) | Geenius (assay interpretati | HIV-1 RNA | HIV-1 TNA (or DNA) | HIV-2 RNA | HIV-2 TNA | Unblinded SRV result summary text |
|------------------|------------------------------|---|-----------------|-----------------------------|-----------------|-----------------|---|
| 3b PrEP no | Reactive x1 or 2 or 3 | Negative | Not Detected | Not required | Not required | Not required | 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. |
| 4 | Reactive x1 or 2 or 3 | HIV1 indeterminate or HIV1 positive | Not Detected | Not detected | Not required | Not required | 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. |
| 5 | Reactive x1 or 2 or 3 | Negative, or HIV1 indeterminate, or HIV1 positive | Detected | Not required | Not required | Not required | Presumptive HIV-1 Infected, based on a single blood specimen. Recommend further testing for confirmation. Please draw a new sample per service testing requirements and submit using visit type "Confirmation/CFM". |
| 6 | Reactive x1 or 2 or 3 | Negative, or HIV1 indeterminate, or HIV1 positive | Not Detected | Detected | Not required | Not required | Presumptive HIV-1 Infected, based on a single blood specimen. Recommend further testing for confirmation. Please draw a new sample per service testing requirements and submit using visit type "Confirmation/CFM". |
| 7 | Reactive x1 or 2 or 3 | HIV2 Positive | Not detected | Not required | Not required | Not required | Presumptive HIV-2 Infected, based on a single blood specimen. Recommend further testing for confirmation. Please draw a new sample per service testing requirements and submit using visit type "Confirmation/CFM". |

| | ECR (EIA/ CMIA/ Rapid) | Geenius (assay interpretati | HIV-1 RNA | HIV-1 TNA (or DNA) | HIV-2 RNA | HIV-2 TNA | Unblinded SRV result summary text |
|----|---|-----------------------------------|-----------------|-----------------------------|-----------------|-----------------|--|
| 8 | Reactive x1 or 2 or 3 | HIV Positive- Untypable | Not detected | Not detected | Detected | Not detected | Presumptive HIV-2 Infected, based on a single blood specimen. Recommend further testing for confirmation. Please draw a new sample per service testing requirements and submit using visit type "Confirmation/CFM". |
| 9 | Reactive x1 or 2 or 3 | HIV Positive- Untypable | Not detected | Not detected | Not detected | Detected | Presumptive HIV-2 Infected, based on a single blood specimen. Recommend further testing for confirmation. Please draw a new sample per service testing requirements and submit using visit type "Confirmation/CFM". |
| 10 | Reactive x1 or 2 or 3 | HIV Positive- Untypable | Detected | Not required | Detected | Not required | Presumptive HIV-1 and HIV-2 Infected, based on a single blood specimen. Recommend further testing for confirmation. Please draw a new sample per service testing requirements and submit using visit type "Confirmation/CFM". |
| 11 | Reactive x1 or 2 or 3 | HIV Positive- Untypable | Not detected | Detected | Not detected | Detected | Presumptive HIV-1 and HIV-2 Infected, based on a single blood specimen. Recommend further testing for confirmation. Please draw a new sample per service testing requirements and submit using visit type "Confirmation/CFM". |
| 12 | Non- reactive x2 + Antigen reactive Abbott Determine | Negative | Not Detected | Not required | Not required | Not required | No evidence of infection with HIV-1/2 and no evidence of vaccine- induced seropositivity/ reactivity (VISP/R). These results (antigen reactivity with non-detectable RNA results) are consistent with non-specific cross- reactivity (false reactive, not VISP/R). |

Vaccine Routine algorithm (visit = VST)

Figure 30: Vaccine Routine algorithm

Vaccine Routine

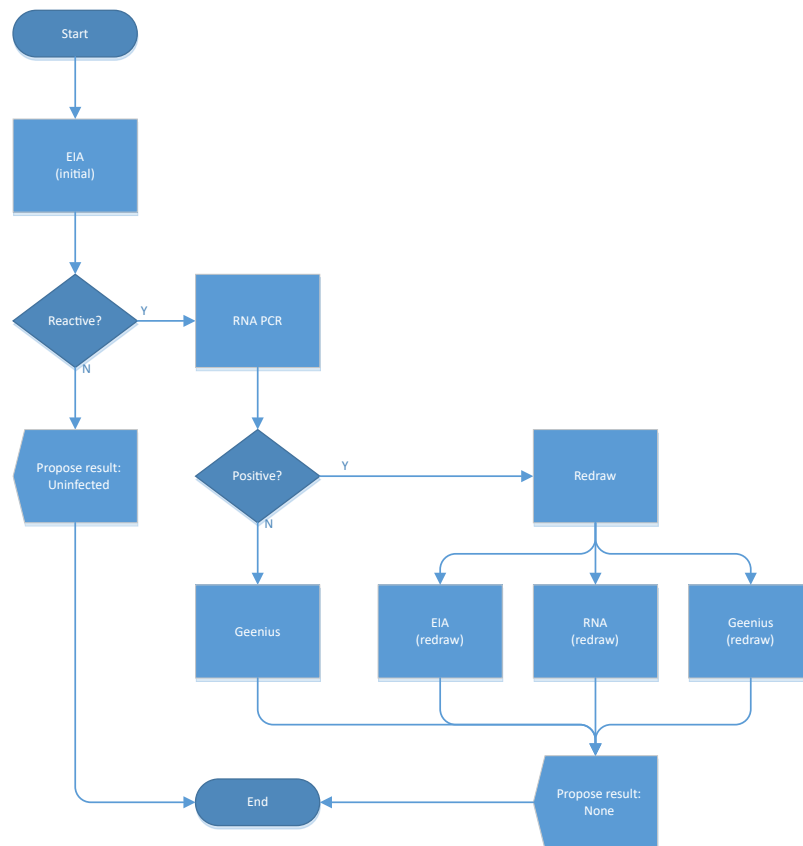


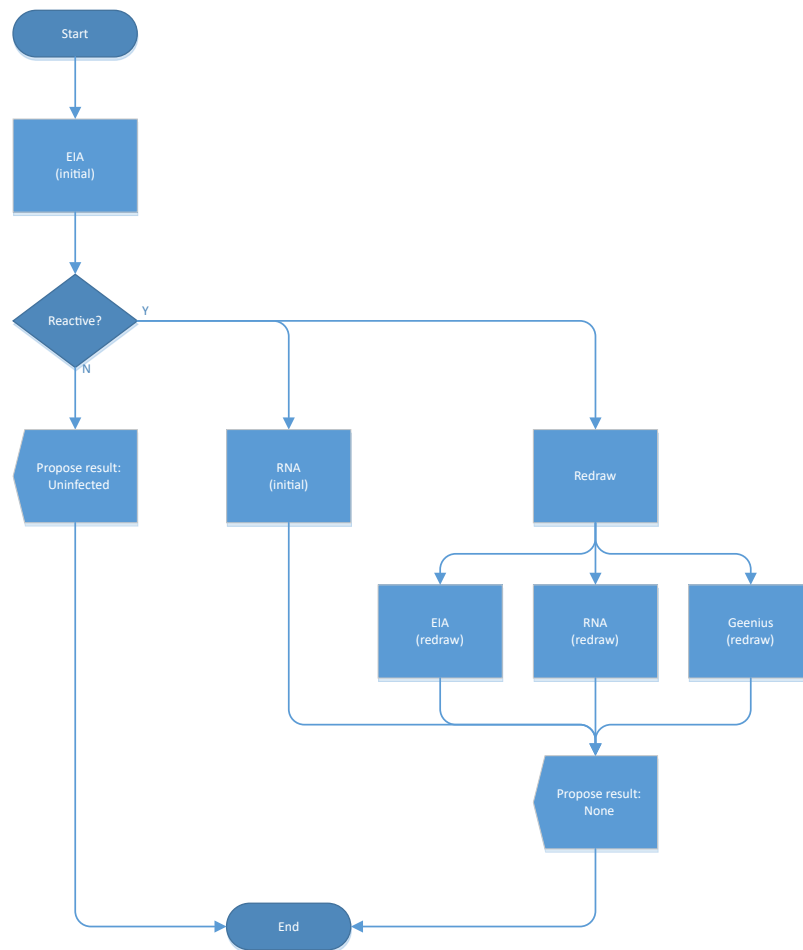
Table 7: VST Algorithm - Unblinded Report Summary Comments

| ECR (EIA/CMIA/ Rapid) | HIV-1 RNA | Geenius | HIV-1 TNA (or DNA) | Unblinded VST result summary text |
|----------------------------------|----------------------|----------------|-----------------------------------|---|
| Non-reactive x1 ECR | Not detected | Not required | Not required | No evidence of infection with HIV-1 or HIV-2. |
| Non-reactive x1 ECR | Not detected | Any | Not required | No evidence of infection with HIV-1 or HIV-2. |
| Reactive or Equivocal x1 ECR | Not detected | Not required | Not required | No evidence of infection with HIV-1 or HIV-2. These results may indicate vaccine-induced sero- reactivity, or these results may be due to non-specific serological cross-reactivity. No further testing is required at this time. Vaccine- induced sero-reactivity will be confirmed at the end of the study. |
| Reactive or Equivocal x1 ECR | Not detected | Any | Not required | No evidence of infection with HIV-1 or HIV-2. These results may indicate vaccine-induced sero- reactivity, or these results may be due to non-specific serological cross-reactivity. No further testing is required at this time. Vaccine- induced sero-reactivity will be confirmed at the end of the study. |
| Reactive or Equivocal x1 ECR | Detected | Any | Not required | HIV-1 Infected |

mAb Routine Algorithm (visit = VST)

Figure 31: mAb Routine algorithm

mAb Routine



| ECR Criteria | RNA Criteria | DNA Criteria | Pass | Proposed Algorithm Result Summary |
|------------------------------|--------------|--------------|------|--|
| Non-reactive x1 ECR | Not required | Not required | 1 | No evidence of infection with HIV-1 or HIV-2. |
| Reactive or Equivocal 1x ECR | Not required | Not required | 1 | Further Testing Required. Draw new sample per protocol requirements and submit using visit type Redraw/RDW |

Minimal Post-Study Algorithm

Figure 32: Minimal Post-Study Algorithm

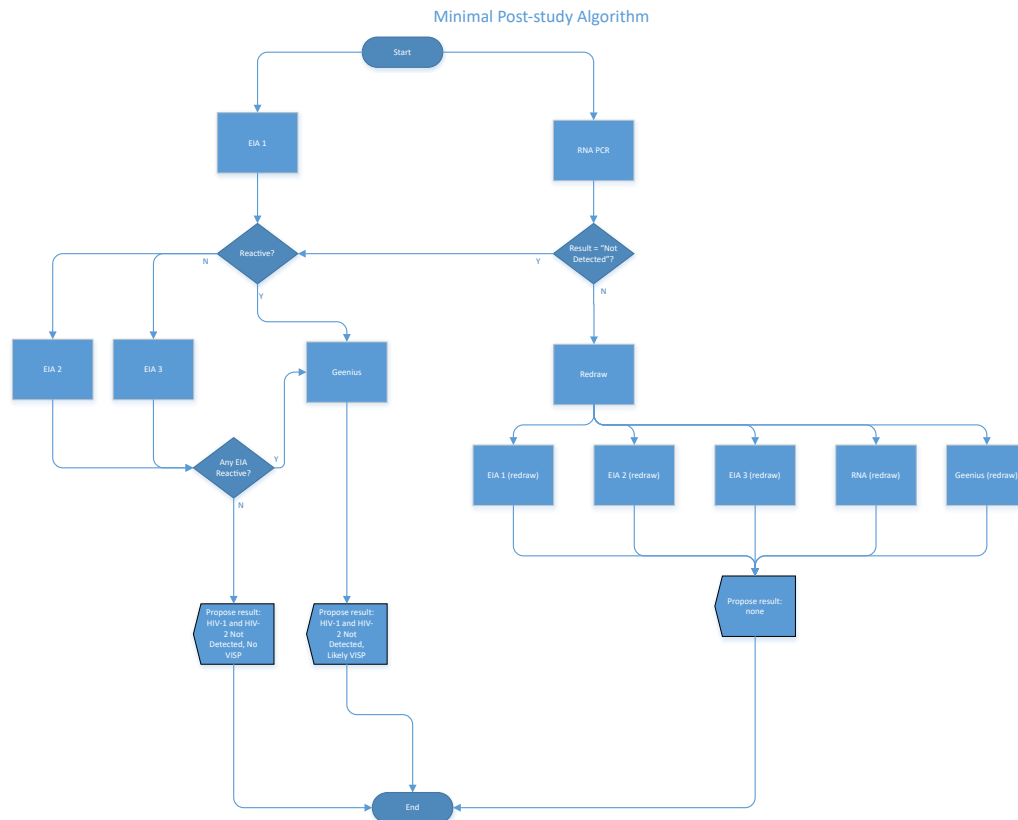


Table 8: Minimal Post-Study Algorithm – Unblinded Report Summary Comments

| | ECR (EIA/CMIA/Rapid) | Geenius (assay interpretation) | HIV-1 RNA | HIV-1 TNA (or DNA) | HIV-2 RNA | HIV-2 TNA | Unblinded POS result summary text |
|---|-----------------------|--------------------------------|--------------|--------------------|--------------|--------------|---|
| 1 | Non-reactive x3 ECR | Not required | Not detected | Not required | Not required | Not required | No evidence of infection with HIV-1 or HIV-2. No evidence of vaccine-induced seroreactivity or non-specific serological cross-reactivity. If any previous HVTN HIV diagnostic test results showed evidence of vaccine-induced seroreactivity, it is recommended that HIV diagnostic testing continue through the HVTN until no evidence of seroreactivity is repeatedly demonstrated. |
| 2 | Reactive x1 or 2 or 3 | Negative | Not detected | Not detected | Not required | Not required | No evidence of infection with HIV-1 or HIV-2. These results are consistent with vaccine-induced seroreactivity, if participant received vaccine product, or these results may be due to non-specific serological cross-reactivity. |

| | ECR (EIA/ CMIA/Rapid) | Geenius (assay interpretation) | HIV-1 RNA | HIV-1 TNA (or DNA) | HIV-2 RNA | HIV-2 TNA | Unblinded POS result summary text |
|----|----------------------------------|---|----------------------|---------------------------------------|----------------------|----------------------|--|
| 3 | Reactive x1 or 2 or 3 | HIV-1 Indeterminate or HIV-1 Positive (consistent with product) | Not detected | Not detected | Not required | Not required | 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. |
| 4 | Reactive x1 or 2 or 3 | Negative or HIV-1 Indeterminate or HIV-1 Positive or HIV Positive, Untypable | Detected | Not required | Not required | Not required | Infected, HIV-1 |
| 5 | Reactive x1 or 2 or 3 | Negative or HIV-1 Indeterminate or HIV-1 Positive or HIV Positive, Untypable | Not detected | Detected | Not required | Not required | Infected, HIV-1 |
| 6a | Reactive x1 or 2 or 3 | HIV-2 Positive | Not detected | Not required | Detected | Not required | Infected, HIV-2 |
| 6b | Reactive x1 or 2 or 3 | HIV-2 Positive | Not detected | Not required | Not detected | Detected | Infected, HIV-2 |
| 7a | Reactive x1 or 2 or 3 | HIV-2 Indeterminate | Not detected | Not required | Detected | Not required | Infected, HIV-2 |
| 7b | Reactive x1 or 2 or 3 | HIV-2 Indeterminate | Not detected | Not required | Not detected | Detected | Infected, HIV-2 |
| 8a | Reactive x1 or 2 or 3 | HIV Positive, Untypable | Not detected | Not detected | Detected | Not detected | Infected, HIV-2 |
| 8b | Reactive x1 or 2 or 3 | HIV Positive, Untypable | Not detected | Not detected | Not detected | Detected | Infected, HIV-2 |
| 9a | Reactive x1 or 2 or 3 | HIV Positive, Untypable | Detected | Not required | Detected | Not required | Infected, HIV-1 and HIV-2 |

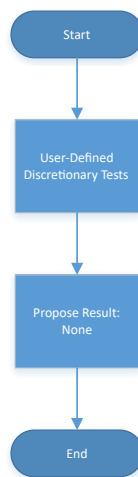
| | ECR (EIA/ CMIA/Rapid) | Geenius (assay interpretation) | HIV-1 RNA | HIV-1 TNA (or DNA) | HIV-2 RNA | HIV-2 TNA | Unblinded POS result summary text |
|----|--|-----------------------------------|-----------------|-----------------------------|-----------------|-----------------|--|
| 9b | Reactive x1 or 2 or 3 | HIV Positive, Untypable | Not detected | Detected | Not detected | Detected | Infected, HIV-1 and HIV-2 |
| 10 | Non-reactive x2 + Antigen reactive Abbott Determine | Negative | Not Detected | Not required | Not required | Not required | No evidence of infection with HIV-1/2 and no evidence of vaccine- induced seropositivity/ reactivity (VISPR). These results (antigen reactivity with non- detectable RNA results) are consistent with non- specific cross- reactivity (false reactive, not VISPR). |

| Criteria | Result |
|---|---|
| RNA is Detected | Standard redraw is triggered (SubmitRedraw, ReceiveRedraw, EIA, Geenius, RNA PCR) |
| EIA is Reactive | Geenius is triggered |
| EIA 2 or 3 are Reactive | Geenius is triggered |
| EIA is Non-reactive | EIA 2 and EIA 3 tests are triggered |
| RNA was positive and a redraw was triggered | HAWS will propose no result |
| All EIAs were Non-reactive | HAWS will propose Uninfected with no evidence of VISPR |
| At least one EIA was Reactive | HAWS will propose Uninfected, likely VISPR |

Open Discretionary Algorithm

Figure 33: Open Discretionary Algorithm

Open Discretionary



The Open Discretionary Algorithm does not automatically order any tests. This workflow allows the user to manually add any discretionary tests or redraws that they require before setting a final result and generating a final report.

Blinded and Unblinded Report Summary Results:

- No evidence of infection with HIV-1
- No evidence of infection with HIV-2
- No evidence of infection with HIV-1 or HIV-2
- HIV-1 Infected
- HIV-2 Infected
- HIV-1 and HIV-2 Infected
- Inconclusive

Glossary of terms

final report task

Task for generating the final workflow report after a workflow is completed.
Also known as: Report

process assay task

Workflow task for entering assay results

Also known as: ProcessAssay

receive redraw task

Process a specimen that has been redrawn by selecting the specimen from a new visit.

reassign specimen for a test

Change the specimen assigned to be tested on an assay.
Also known as: ResultAlgorithm

review assay task

Workflow task for reviewing and approving assay runs

select sample task

Workflow task for selecting the specimen to be tested.
Also known as: SelectSample

submit redraw task

Workflow task for initiating the redraw of a specimen, such as when the final result is QNS.

Revision history

| Manual Version | HAWS Version | Date | Summary |
|----------------|--------------|------------|---|
| - | 7.2.0 | 2025-12-10 | HAWS 7.2. No user manual updates needed. |
| - | 7.1.0 | 2024-10-22 | HAWS 7.1 updates. Updated Evaluation of Sero-reactivity, Evaluation of Sero-reactivity Recent Exposure, Post Study, and Minimal Post Study algorithms to reflect that HAWS triggers 3 EIA tests when a redraw is received. Updated language in Tasks section to reflect that the HIV-1 and HIV-2 interpretation fields in the Bio-Rad Geenius HIV 1/2 Confirmatory assay data entry screens are required. |
| - | 7.0.0 | 2024-01-05 | HAWS 7.0 updates. Updates throughout to reflect the fact that HAWS is able to sync with web LDMS data. Added Open Discretionary Algorithm and Evaluation of Sero-Reactivity Recent Exposure (EOX) algorithm. Added new assay kits to the following assays: Alere, DNA PCR, EIA, HIV RNA PCR. Added result option "Inconclusive" to Geenius test. Updated DNA PCR result option "Positive" to "Detected" and "Negative" to "Not Detected". |
| - | 6.4.0 | 2022-05-16 | Added "Minimal Post-Study Algorithm – Unblinded Report Summary Comments" table to Minimal Post-Study algorithm section |

| Manual Version | HAWS Version | Date | Summary |
|----------------|--------------|------------|---|
| - | 6.4.0 | 2022-01-18 | Added new section in Algorithms - Minimal Post-Study Algorithm |
| - | 6.3.0 | 2021-02-16 | Updated "Location Administration" section |
| - | 6.2.0 | 2020-11-07 | Updated "Backup Management" section; updated "Supported Assays" section to include "SD Bioline EIA test" kit and "Determine HIV Early Detect" Alere kit |
| - | 6.1.0 | 2020-05-06 | Added option to "Adding a Discretionary Redraw to a Workflow" section about whether the ECR/Geenius/RNA PCR tests should be automatically created |
| - | 6.0.0 | 2019-10-01 | Clinic UI screen updated; added "alere HIV Combo" as new kit; algorithm diagrams and charts updated |
| - | 5.5.0 | 2019-03-12 | Removed erroneously included section; fixed algorithm descriptions |
| - | 5.5.0 | 2018-11-01 | Updated remainder of algorithms to newer style; Updated available reports and assays sections |
| - | 5.4.0 | 2018-07-10 | HAWS 5.4 updates <ul style="list-style-type: none"> • Routine algorithm for AMP protocols • Recent exposure/acute infection algorithm for AMP protocols • Redraw algorithm phase for AMP protocols |
| - | 5.3.0 | 2018-03-23 | HAWS 5.3 updates |
| - | 5.2.1 | 2017-09-19 | HAWS 5.2.1 hotfix updates |
| - | 5.1 | 2017-05-31 | HAWS 5.1 updates |
| - | 5.0 | 2017-03-10 | HAWS 5.0 updates |

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