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1 Introduction

The HistoTrac User’s Manual presents HistoTrac, menu by menu, for the user to understand each of the software’s functions and features. Screen views from HistoTrac are used to show examples of the features that are described in the text.

The organization of the manual coincides with the Menu listing on the left side of the screen. An overview of the System Navigation tools, used to move through the software, is provided before moving to the menu descriptions. The System Menu, located above the Tool bar, presents the feature-setting parameters that apply to the system as a whole. The menu bar begins with Patients and ends with Administration. Administration is the data dictionary for the software.

This manual describes mainly the features of the HistoTrac Core software.

Other modules listed below may be referred to throughout the manual.

- Electronic Signature
- HIPAA Auditing
- Infectious Disease Testing
- Microsatellite Testing
- Process Management for Tests, Samples, and Patients
- Red Cell Typing
- Report Manager
- Label printing
- UNOS module with PRA upload
- UNOS Wait List Management

Two frequently used modules, Batch Test Management and Tray Management, are described in detail, following Administration.
2 System Navigation

2.1 Software Log in

HistoTrac, version 2, is installed with the ‘administrator’ user in the User table.

To log in initially,
1. Double-click the HistoTrac icon on the desktop or locate the application in the Programs listing.
2. Enter ‘hlaadmin’ as the user name.
3. Enter ‘hlaadmin’ as the password.
4. HistoTrac2 is usually the database name in the ‘Log on to’ window. Your system administrator responsible for installation of the software may have used a different name. If you have a test database as well as a production database, there will be more than one choice in this drop-down.

HistoTrac, version 2, Splash Screen

This user has been established with permission to all functionality in the software. Once logged into the software, additional users are added in the Security Dictionary under the Administration menu.

The User Name defaults to the User Name of the Windows login person.

The software opens to the My Patients menu. Your list view will be empty initially.

The frame of the screen will display in parentheses 1) the name of the database (HistoTrac2), 2) the name of the logged in user (Demo, Joe), and 3) the version of the software client (2.0.42).

My Patients List View - as software opens
2.2 Menus

The HistoTrac menu selections are listed down the left side of the screen. After selecting the menu, click a submenu to populate the screen. For example, select the Sample menu. Then click 'Log' to populate the screen with the logbook list view. Each menu has several/many submenus.

Sample Menu, Log Book List View

Once a list view has been populated, moving to a new menu and returning to the first will not refresh the original screen. If content has been added to the database since the previous visit to the screen, use the Refresh button on the Tool bar to ask the system to add new content to the list view.

The order of the menu bar follows the progression of testing in the laboratory. From the Sample Menu through the Sign Off Menu, work moves from sample accessioning and test ordering through review and sign off of the test results. Below Sign Off, other functions of the Core software are presented (Inventory, Billing, and Ad Hoc Query). Other modules with menu listings follow, if the user has licensed those modules. The last menu item is Administration, the data dictionary section of the Core software.

2.3 Tool Bar

The Tool bar across the top of the screen changes depending of the functionality required for a selected menu and submenu. The functions available from the Tool bar are also accessible on a small pop-up menu using the right-click of the mouse.
2.4 Save, Close, and New buttons

After adding/editing field content on any screen, press the ‘Save’ key to save the information before pressing ‘Close’ to close the screen. On some screens, pressing ‘Save’ will create a record in the database that then allows other folder choices to become available. For example on the Sample log when a New Sample screen is opened, save the sample and the system will provide the Orders (and others) menu.

The New button is located to the left of the Save button on many screens. Pressing New will clear the screen for entry of a new record.

2.5 Keyboard or mouse navigation

Use the mouse or the tab key to move from field to field, selecting from the drop-downs or entering free text. The tab order on each screen has been set to move from one field to the next down the screen. Enter the first letter of a choice from a drop-down to move the cursor to that letter on the alphabetical drop-down list. The user can mix mouse navigation with keyboard entry.

2.6 Print reports

Reports are available on all screens where the Print icon is available on the Tool Bar. A report list is available just below the activated Print icon for selection of the desired report. The Print button on the Patient Menu will provide a list of patient-related reports. The Print button on the Sample Menu will provide reports associated with samples. And so on.
3 Customize View Column Headers

The user has the ability to customize the column headers on each list view throughout the software, and to sort and filter the records on the list. The software provides a choice of headers, which can be displayed in a certain order, with a corresponding column width. The Sample Log list view shows column headers as set up in the example below.

The Customize View feature is available on all Patient/Donor, Sample, Work Management, Review, Sign Off, Inventory, and Administration screens. Other modules contain screens that use this feature as well.

To access the Customize View feature, right-click the mouse anywhere on the list view and choose ‘Customize View’ from the pop-up menu.

3.1 Column Header selection and order

Select Customize View from the popup menu. Press ‘Fields’ to view the fields available to select as column headers.

Customize View Screens

The ‘Show Fields’ screen presents Available Fields on the left. To add fields to the window on the right, either double-click the mouse or use the ‘Add’ and ‘Remove’ arrow buttons. Use the ‘Move Up’ and ‘Move Down’ buttons, changing the position of the selected fields to obtain the order desired. In the column header example at the bottom of the Show Fields screen, adjust column size (after selection of the fields) to accommodate the field content. Press OK to save these settings. Close the View Summary screen and the list view will change to reflect your column selections.

3.2 Filter By

To obtain a subset of the original content of the list view, use Customize View and press the ‘Filter By’ button. In this example, only patients with a Category of ‘renal’ will appear on the list view. Remove the filter to return to the full listing.
3.3 Sort Order

To manage the order in which list view entries are seen, use Customize View and press the 'Sort' button. The example below will provide a list starting with the oldest sample date and ending with the newest date. To display the newest sample date at the top of the list, choose Descending. Several sort instructions can be used. For example, sort by Sample Date, and then my Last Name, then First Name. Remove the sort criteria by selecting ‘None’ from the drop-down.

3.4 Copy Column Headers to other users

Selected column headers are user specific. Once the column headers have been selected that best suit the laboratory’s choices, these choices can be copied to all users. A suggested approach is to identify one user who is responsible for setting up each screen. Then copy these choices to the other users.

In Administration, go to the Security Dictionary. Select the User folder. Open a User record to which the columns are to be copied. Press the Copy Screen Setup button. From the Copy From User drop-down, select the user whose column headers have been set up. Press OK and the user will now display the same screen headers upon log in.

If the entire user table is to be updated with the new column headers, check the Copy to All Users check box. Press OK.
4 System Menu Bar

Above the Tool bar is the System Menu bar. The several menu selections provide for setting of parameters that relate to the functioning the system as a whole. The Administration Menu is the data dictionary specific to Patient, Sample, Test, Reports, and Security. Settings available from the System Menu apply to the general use of the system. There are some features that require coordination between the Data Dictionaries and the System Menu choices.

4.1 File

The File menu shows the same functions that are seen on the Tool bar. The Tool bar shortcut keys are listed along with the tool bar function.

File Menu with Submenus

4.2 Tools

The Tools menu provides several submenus – Options, Tool Bar Key Map, System Function Key Map, and Screen Help.

Tools Menu with Submenus

4.2.1 Options

Use the System Options screen to set many system parameters. Each tab contains settings that determine some system default values.
4.2.1.1 System

System Options – System tab

1. Enter the name of your laboratory and address. This information will appear on the top of some internal reports.

2. Select the date format to be used in your location. The available choices accommodate US and international formats. Synchronize the choice with the overall system format.

3. Edit Non-Working Days. The Turn Around Time (TAT) for the Overdue tests function (Work Management/Overdue tests) will calculate prospective TAT. The calculation can include all days on the calendar or can take into account the days that the laboratory is not open for service. Press the Edit Non-Working Days button.
   a. Check the Include Weekend? Check box to include weekend days in the non-working days group. This selection will exclude weekend days from the prospective TAT calculation.
   b. Double click an days that are considered holidays. All red dates will be included in the non-working days group.
   c. Save the choices.
4. Use Country Code with Phone Numbers checkbox is for international users, or users who service international clients. The various records throughout the software that have phone numbers will show a field for the country code.

5. Default to Test Batteries when Ordering will display the Batteries tab first when using the Add Order feature on the Sample record.

4.2.1.2 Patient

**System Options - Patient tab**

1. When using the Patient Menu, the system will provide a search screen immediately after selecting the Patient or Donor folder under the menu. Because there are many patients and donors in your database, checking the ‘Search before Displaying Log’ is recommended. Alternatively, without the search screen, the patient list view will populate with the maximum number of records each time the menu is selected.

2. Enter a maximum number of records to be returned by a search. Select a value that will provide all of your search records without being excessive.

3. The ‘Auto-Generate Patient Number’ should be checked if you use an internal patient ID number and wish the system to automatically generate that number. The format of the number is established in Administration under the Patient Dictionary/Patient Number Generator.

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4.2.1.3 Sample Options – Sample tab

1. When using the Sample Menu, the system will provide either a search screen immediately after selecting the Log folder, or it will display the maximum number of records. Typically, the user will want to see a list view of the last samples accessioned into the lab. If so, do not check the ‘Search for Sample before Displaying Log’. To view the last samples accessioned, use Customize View on the Sample log and sort the logged date in descending order. If trying to locate an individual sample, use the ‘Find’ button on the Tool bar.

2. Set the ‘Maximum Samples returned from search’ at a reasonable number to display a day, week or month’s samples.

3. Select a ‘Default Specimen Type’ from the drop-down. This drop-down contains the choices from the Specimen Type table in Administration under Sample dictionary. The choice should reflect the specimen type most commonly received. The value can be changed on the Sample screen when other specimen types are received. If multiple logbooks are in use, this choice will default on all logs.

4. Select a ‘Default Specimen Count’. This value should reflect the number of tube(s) received for the default specimen type.

5. Check the ‘Require a Sample Time’ check box if your laboratory policy is to require entry of the time the sample was collected. The system will not allow the closure of the sample screen unless this field contains a value. If the Sample Time is accurately represented by the current time when the sample is logged in, check the ‘Default Sample Time to Current Time’.

6. The ‘Default Log Book’ choice allows the user with multiple logbooks to have the most commonly used log appear first when selecting Log under the Sample Menu. The log can be changed using the drop-down at the top of the list view.

7. The ‘Default Provider Type’ choice determines the value in the Provider Type field on the Sample record. If the laboratory tests only donors, choose a default value of Donor. Otherwise select Patient.
8. ‘Ordering Physician’ is a drop-down on the Sample record. The Ordering Physician can be displayed from the drop-down either with the Name field or the Code field as the primary key. If you wish to use the alpha character of the physician’s name to select from the drop-down, use the ‘Display by Physician Name’.

4.2.1.4 Reports

System Options – Reports tab

1. Each time a patient or donor ‘Official’ report is printed, the system will write the report to a .pdf file. If the user wishes to save electronic copies of all printed reports, check the box ‘Generate PDF for All ‘Official’ Patient Reports’. The report files are stored on your system directory in the location entered into the ‘Generate PDF Files to the following directory’. The reports are not stored within the HistoTrac software, but separately, on a drive available to all workstations. (Each time a .pdf report is created, the file path is listed on the patient’s record on the Report history screen.)

2. A part of the Report Manager scheduling module is the ability to automatically print a report for the laboratory. If using the Report Manager, check ‘Print Reports for the Laboratory’.

3. If you are printing a report to a fax machine, select the appropriate fax from the drop-down.

4. The ‘Default Tray Report’ is used with the Tray Management module. Select the Tray Map report that will be printed from the Tray Wizard when creating a tray from a batch or on the Trays screen of the Tray Dictionary/Trays folder. This report will appear when pressing the ‘Print Tray Layout’ button.
4.2.1.5 Test

System Options – Test tab

1. Select the 'Default Test Priority' to automatically populate the Priority field when ordering a test. Choose the priority most commonly used. The value can be changed when ordering tests of a different priority.

2. To make positive or negative antibody results more visible on the patient's Antibody History screen, select a value from the 'Highlight Antibody Results with the following Result' drop down. This is populated from the table in the Test Dictionary called Antibody Result Codes. It is used for tests with a positive or negative type of result value.

3. The same feature is present for antibody tests with a % Positive result value. Check the 'Highlight Non-Zero Antibody' check box to make positive results more prominent on the patient's Antibody History screen.

4. The Default Charge To field is used when an automated billing interface is in place.

5. The two choices 'Consider this as the Antibody Class I (Class II) Code' provide the system with the ability to update the Peak and Current PRA fields on the patient's Antibody History screen (see example below). The antibody test definition must include a Cell field. The user must have completed this field when entering test results (or by default during test definition) with a choice from the Antibody Cell Type Codes in

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Administration/Test Dictionary. Selecting a value on the Options/Test screen allows the system to know what terminology the user has chosen to designate Class I and Class II results.

Test Definition and System Options set up for Antibody History Update

- **Patient Antibody History with Peak and Current Fields updated**

- **4.2.1.6 Case**

System Options - Case tab

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1. Case numbers can be generated by the system, entered by the user, or coded for a particular code format. To allow the system to generate the case number automatically when creating a new case, check the ‘Auto-Generate Case Number’ check box.

2. Establish the format for the case number in the Case Number Format window. The number ‘9’ codes for a number. Alpha characters can be used. Numbers can be used, with or without alpha prefixes. The example will yield a six-digit number. The next number generated will follow the number entered into the ‘Last Case Number’ field. The code and number sequence can be formatted to provide a sequential number following one already in use in a previous system. If the user wishes to generate the case number using one or more format codes, leave the check box unchecked and set up a format code in the Administration, under the Patient dictionary.

3. ‘Activate Case When Adding a Donor’ is a setting to be used if donors are added to already existing cases that have been signed out. When the donor is added to an existing patient case, the status will change to Active and the case will be listed on the Review or Sign out by Case screen.

4. When using the Report Manager, a report printing scheduler, check the ‘Auto-generate Case Report’ check box. Select from the Case Report drop-down, the report that should be automatically printed when a case is signed out.

5. Cases, like tests, can be set for a number of review cycles. Since test results appear under case review after the test has been signed out, the number of steps of case review should be established in conjunction with the review process for tests. If tests are being reviewed in two steps, case review may require only one step. If tests are set for one step, cases may be set for two, to allow for review of the comments entered associated with the case.

6. Active cases will appear in the Review and Sign Off menus under the submenu By Case. If a case has been completed and all members’ tests have been signed out, the case can be inactivated to remove it from the Review By Case list view. To allow the system to make the case inactive automatically after sign off, check the ‘Inactivate Case After Sign Off’ check box.

7. When creating a case, either on the Sample screen or the Patient screen, the patient is automatically added to the case. Select the relationship from the drop-down that will be applied to the patient upon creation of the case. This is necessary because the relationship table is user-defined and the relationship is a required field.

4.2.1.7 Sign Off

System Options – Sign Off tab

1. Each patient’s record contains a field called ‘Last Typed Date’ for both serological typings and molecular typings. This field is populated by the system when a serological or molecular typing is signed out. The Last Typed Date is often placed on reports. Users have a choice of date fields, associated with the test, used to populate that field. The Typed Date can be the Ordered Date, or Completed Date, or Signed out Date. Select a value from the drop-down.
2. Print Reports for a donor based on the active case for the associated patient’ is a feature used to add a new donor’s test results to an existing patient’s case report. If the new donor’s testing is on the Sign Out list, but not any of the patient’s tests, selection of a Case Report from the donor test, will place the donor on case report of the patient in which the donor is a case member. This feature is useful if the donor is in only one patient case.

3. ‘Do NOT allow Result, Review, and Signoff by the same user’ prohibits the same user from moving tests through the sign out process, requiring review by at least one other user.

4. ‘Require Password to Electronic Signature Sign Off’ presents a password entry screen at the Save and Close event on the Sign Off Complete set. If tests are moving through an HL7 interface, director electronic signature prior to sending the test would be appropriate.

4.2.1.8 Inventory Location

**System Options - Inventory Location tab**

1. The ‘Auto-Fill all Inventory Locations’ provides an instruction for the system to locate an available position within a selected inventory location. Check the checkbox to activate this feature. When the user opens an inventory screen for placement of a sample, the user selects the location and the system will identify the next available empty grid. The user presses the ‘Add’ button for each addition of the sample to inventory. This feature can be used in conjunction with the AutoFill mechanism on the Storage Location set up screen. That AutoFill feature will present the user with the next available location as well as the next available grid.

2. The ‘Show Column Labels as Letters’ and the ‘Show Row Labels as Letters’ allows the user to identify the rows and columns of contains as they are marked. Leave both boxes unchecked to have rows and columns each labeled with numbers. Check either Columns or Rows, or both, to be displayed as letters.

3. Leave the ‘Always Show DNA and Sera Locations when adding Sample to Inventory’ unchecked if you want only DNA locations available on the DNA Extraction screen and only Serum locations available from the inventory folder on the Sample record. If the check box is checked, the DNA inventory and the Serum inventory will be available from the Locations folder on the Sample record, The Place Samples into Inventory button on the Results screen, the Review screen and the Sign out screen continue to offer only the Serum inventory.
4.2.1.9 HIPAA (available with the HIPAA Auditing Module)

**System Options - HIPAA tab**

1. Policies and Procedures for HIPAA regulations can be viewed while in HistoTrac. Point the system to the directory where the policy and procedure documents are stored.

2. The system will audit all activity associated with patient, sample, and test records. If the user wishes to audit only some database transactions, check the box next to the desired transactions. For full auditing of all transactions, check the Adds, Changes, Deletes, and Views for Patients, Samples, and Tests. The audit trail is available under the HIPAA menu on the System Menu bar.

4.2.1.10 Purchasing (available with the Purchasing Module)

**System Options - Purchasing tab**

1. The Purchasing Module uses Purchase Order forms. The form contains a Ship To Address. The user can enter a default Ship To contact and address to populate the form automatically.

4.2.1.11 Security

The Security settings allow the user to implement requirements for the user’s password access to the software.

**System Options - Security tab**
1. Password expiration can be set at zero (0) if no expiration is desired. Enter the number of days if expiration feature is to be used. The software will provide a message, alerting the user for the need to change passwords. The user can go to Administration/Security Dictionary/User to change password. For users who do not have permission to use the Administration menu, go to the Help menu choice of the System tool bar. Use the Change Password option. See 4.5.3 below under the Help section.

2. Password characteristics can be determined by entering a value for the following:
   a. Minimum length in days (or 0 for no minimum requirement)
   b. Require Upper Case Characters
   c. Require Lower Case Characters
   d. Require Number Characters
   e. Require Special Characters
   If all choices are needed, check each.

3. ‘Automatically Sign Off Inactive User’ will log the user out after the specified number of minutes.

4.2.1.12 Match Run (available with the Final Crossmatch module)

The Final Crossmatch Module allows for the import of a UNOS Match Run file and the reporting of crossmatch results on selected recipients in the file. Samples can be system selected for placement on crossmatch trays. Tests can be ordered and resulted, requiring the system to create a case between the donor and any selected patient.

System Options – Match Run tab

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To accomplish the set up for sample selection and the reporting process, the user must

1. Enter the UNOS codes of patients whose samples are to be selected from the Match Run listing. (UNOS Codes for local samples). Use a comma to separate multiple entries.
2. Define the age of a ‘current’ sample. (Number of days before a sample is not considered current).
3. Allow the system to auto select the current samples or allow the user to manually select. (Checkbox for ‘Auto Select Crossmatch Samples’).
4. Define interpretation of multiple scores (from HistoScope). The patient may be tested with multiple samples on the cytotoxicity tray. When the scores are imported from HistoScope, the multiple sera reactions need to be converted to an overall result for Class I or Class II before resulting the selected test. Enter into the ‘Any Scores with (8’s, 6’s, 4’s, 2’s, 1’s), the result associated with those scores. For example, if three scores are imported for a patient and the scores are 1, 2, and 8, the system will need to know whether to result that as Positive or Negative.
5. Select the Crossmatch Test code that will be ordered when the scores or results are input. (Crossmatch Tests for Match Run.) The drop-down will contain all active Crossmatch tests in the Test Dictionary.
6. Define the case numbering prefix that is to be used when the system creates a case between the donor and any patient without an existing case. (Case Number Prefix). The Case numbering format is set up in the Patient Dictionary.
7. Define the relationship of the donor in the patient’s case. (Donor to Patient Default Relationship)
8. Define the Overall Result value of multiple crossmatch test values. Use the table with Cyto Class I/II and Flow Class I/II with a Result. Enter a result value for all combinations of Positive and Negative results. The number of combinations of results will depend on the number of entries in the Crossmatch Results table of the Test Dictionary.

4.2.1.13 UNOS (available with the PRA Export and the UNOS Waitlist modules)

Two UNOS-related modules require the establishment of settings or cross-reference tables.

**System Options – UNOS tab**

The **UNOS PRA Export** module exports from the Peak and Current PRA fields on the Patient Record, Antibody History screen. The system offers a choice as to which fields will be exported.
1. Check ‘Export Class I PRA Values’ if the Class I Peak and Current are to be included in the export file.
2. Check ‘Export Class II PRA Values’ if the Class II Peak and Current are to be included in the export file.
3. Check ‘Export Highest Class I or Class II PRA Values’ if the higher of the two Peak or two Current are to be included in the export file
4. Check the ‘Update Unacceptables when Exporting to UNOS’ to include the values on the Patient record in the Specificity/Antigen folder, Unacceptable Antigens field, in the export file.

The export file is created under the UNOS menu, ‘Generate PRA file folder.

The **UNOS Wait List Management Module** requires the cross reference between table values in HistoTrac with values used in the UNOS file. The values/codes from the UNOS Wait list file will be loaded in each of the windows on the left. The user can Add and Delete UNOS values using the buttons on each screen. To map the values between...
the two sources, highlight the UNOS value, then the HistoTrac value, and then click the ‘Map’ button. Click the ‘Unmap’ button to reverse.

1. Cross Reference UNOS Categories will link the Organ code in the UNOS Wait List with the content of the HistoTrac Category table in the Patient dictionary.

2. Cross Reference UNOS Blood Types will link the ABO code in the UNOS Wait List with the content of the HistoTrac ABO table in the Patient dictionary.

3. Cross Reference UNOS Races will link the Race/Ethnicity code in the UNOS Wait List with the content of the HistoTrac Race table in the Patient dictionary.
4. Cross Reference UNOS Statuses will link the Status code in the UNOS Wait List with the content of the HistoTrac Status table in the Patient dictionary.

Synchronize the HistoTrac database with the UNOS Wait List file under the UNOS Menu, Wait List folder.

4.2.2 Tool Bar Key Map

Navigation through the software is facilitated by the use of shortcut keys. Instead of using the mouse to select the buttons on the Tool bar, shortcuts on the keyboard can open records, activate a search screen, etc.

For example, press the Ctrl + P keys to active the Print button for a list of reports.

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4.2.3 Screen Help

Each screen contains a help statement area that can be completed by the user. If you have an instruction that you wish to provide your users – something that relates to a requirement you have for entering data – place a reminder in the user-defined help area.

From the Screen Help menu, the Screen Help screen provides access to all screens in the software where a user-defined field is available. Select the screen or log name from the drop-down. Enter the instructions into the Help Text window.

Alternatively, the user-defined help statements can be added directly on each screen. Double-click the hyperlink to access the Screen Help screen. Enter the instruction into the Help Text window.

4.3 Utilities

The Utilities Menu provides a location for accessing other applications from within HistoTrac. The application could be a standard software application such as Word or a custom application that links to the HistoTrac database.
The Utility is pathed to the location of the executable file in the Administration Menu under Utilities.

4.4 HI PAA (for users with the HI PAA Auditing Module)

The HI PAA menu provides access to the Policies and Procedures that may be accessed from within HistoTrac and access to the HI PAA Audit Viewer. (See Tools/Options/Hi PAA for set up of activities to be audited.)

All transactions that are to be audited will appear on the list view. Press Patient Log, Sample Log, or Test Log on the left to view each category of transaction.

Sample Log Audit Trail List View

Press the binoculars on the Tool bar to locate a particular record.
Sample Transactions for a particular patient

4.5 Help

The Help menu provides access to information about your HistoTrac installation, on-line help files, and a quick method of software log off/in.

System Menu – Help with Submenus

4.5.1 About HistoTrac

The version of the HistoTrac application installed is found on the About HistoTrac screen. This screen also provides your software license number.

About HistoTrac

Press the Modules button to see a list of installed modules.

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4.5.2 Help Topics

Select Help Topics to activate the system on-line Help files. These are provided in the Help software RoboHelp.

4.5.3 Change Password

If the Password Expiration feature is turned on under the Tools/Options/Security, the user can change passwords after logging by selecting Change Password under the Help menu.
Enter the Old Password, the New Password and then Confirm New Password. The change will be effective with the next log in session.

4.5.4 Log Off

When a user has finished with the HistoTrac application and another person wishes to immediately log in, select Log Off from the Help menu. The software closes down and provides a new log in screen for the next user.
5 The Patient Menu

The software opens to the My Patient’s screen, a list view of patients and donors, selected from the database for easy access by the logged in user.

My Patient’s List View

From the Patient Menu, select Patient, Donor, or Proficiency to view the provider’s record. Use a search screen on the Tool bar to locate the desired patient.

Patient List View

Select a Patient from the list view and double-click to open the record.

5.1 Patient or Donor Demographics and Test History

Information available for review in the patient or donor’s record is all demographic data, all signed out test results, cases built linking patients and donors, and other patient-specific information. A list of folders down the left side of the screen provides access to all of a patient’s information from the same location.

The donor record has many of the same screens seen on a patient record. However, there are some test types that are not ordered on donors, such as antibody screening tests. Such a test history screen is not available on the donor record.
5.2 General Information

The patient screen opens to the General Information folder. Shown below is a patient’s demographic information and current HLA typing. From this screen, click any of the other folders to view test history or other information.

Patient History Screen – General Information

Donor History Screen – General Information

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5.3 HLA Typing History

The General Information screen shows both the serological and molecular typing results. The values on this screen are considered the patient’s current typing and will print on an official report. The fields are updated with the latest test results that have been signed out.

The HLA typing test history that builds the typing on the General Information screen is found in the Typing History folder. Each test result is summarized on the Typing History list view. To view the complete results of each test, double-click the desired test or click the Edit/View hyperlink.

Test results that have completed the review process move into the history screens. The list view will show ‘pending’ in the Results column if the test has not been through the review and sign out process. Should an erroneous result pass through the sign out process, selected individuals have editing privileges using the ‘Edit Tests’ hyperlink.

![HLA Typing Test History List View Screen](image)

5.4 Antibody History

Antibody Screening test history is shown below. The results of each test appear when the test has been signed out. Until sign out, results are listed as ‘pending’. Use the ‘Customize View’ feature to display and sort the results in the most beneficial order.

![Patient Antibody History Screen](image)

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5.5 Patient Case

The Cases screen shown below presents the members of this particular case, the relationship and HLA typing information for each member. The haplotypes can be aligned and labeled by using the ‘Haplotype Assignment’ hyperlink. Mismatch codes between a patient and any of several donors can be included for use on the final report.

**Patient Case Screen**

5.5.1 Create a Patient Case

To create a patient case, press the Add Case link. On the New Case screen, enter a Case Number or allow the system to auto-number the case. Check the ‘Active?’ checkbox. Save the case.

**New Case Screen**

The new case has a case number, a status of New, and the patient automatically added as a member.
Press the Add Case Member button to add a donor to the case. Enter the donor MRN or SSN or use the search screen to locate the donor. Select a Relationship from the drop-down. Press Save to add the donor to the case.

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5.6 Crossmatching

The Crossmatch tab provides a history of tests done against each donor, with specifics about the test methodology. Double-click each test to view the details of the test.

**Patient History Screen - Crossmatching**

Crossmatch Test Detail

5.7 DNA Extractions

After entry of the DNA extraction data under the Sample menu, the data are stored on the DNA Extractions folder of the provider’s screen. Use this information when ordering additional molecular testing.
5.8 Sample History

The Sample History screen contains a listing of all samples that have been accessioned on the patient. It also provides the location of the sample if it has been entered into inventory.

5.9 Comments

The system provides a number of places for entering comments. The Patient Comments screen is used for entering notes relative to the patient his/herself. Comments fields are provided in other places for test and sample comments. Type free text in the Comments screen. You may want to initial and date each comment for tracking ability over time.
5.10 Reports

The Reports list view shows the file location of all reports that have been created in the .pdf format. Under the Tools menu, Options submenu, Reports tab, the user can instruct the system to automatically create a .pdf-formatted report to be stored in a selected directory. Each time an official report is generated, the .pdf file is created and a record of the file is listed on the Reports screen of the patient or donor.

System Options - Reports tab
5.11 Specificity/ Antigen

The Specificity/Antigens screen is a place to enter the summary of the patient's antibody status. There is a location for both Class I and Class II antibody specificities. Also enter Unacceptable Antigens and Acceptable Antigens. The system automatically logs the fields for Last Updated by and Last Updated Date.

The Batch Period and Batch Method are used as attributes when executing a Batch Accessioning or Batch Ordering rule with the Batch Test Management module.
5.12 UNOS Activity

The UNOS folder provides a place to keep track of the patient's UNOS status and to assist in management of the patient for inclusion on regional screening trays. Use the 'Add Transaction', 'Edit Transaction', and 'Delete Transaction' hyperlinks to manage the patient's UNOS transactions activities.

Patient Screen - UNOS Transactions

5.13 Sensitization History

Transfusions, prior transplants, and pregnancies are entered on the Sensitizing Events screen. This information is helpful when analyzing antibody-screening results. Press the 'Add Event' button for data entry. Use the 'Edit Event' and 'Delete Event' to manage prior entries.

Patient Screen - Sensitization History
5.14 Other Tests

There is often the need to include test results other than histocompatibility tests in the patient’s history. These results would perhaps have been tested in some other laboratory but are of interest in the patient’s total assessment. On the Other Tests screen, click the ‘Add Test’ hyperlink to access a screen for entry of such tests as HCV, CMV, HIV, and HBsAg. Use the ‘Edit Tests’ and ‘Delete Tests’ hyperlinks to manage previously entered tests.

![Other Tests Screen](image)

5.15 Insurance

Maintain your patients’ insurance information on the Insurance screen.

![Patient Screen - Insurance](image)
5.16 Audit History

Keeping track of changes made to the patient’s information is an important quality assurance tool. For the fields that have been selected for auditing in Administration, each time a change is made, the pre and post change values are presented on the Audit History screen. The date of the change and the person who made the change are also documented.
6 The Samples Menu

All activities associated with samples are accomplished from the Samples menu. A logbook called Sample log is provided with the software. The user may create additional logs.

- Samples are added, edited, viewed, and deleted from the Sample screen of the Log menu.
- Tests are ordered from the Sample screen of the Log menu.
- DNA extractions are managed from the DNA Extraction menu.
- If the user has the Batch Test Management module, Batch Accessioning and Batch Ordering are done here as well.

6.1 Log

6.1.1 The Log list view

Under Samples, click Log. The Logbook appearance permits looking at the entries for the last days/weeks at a glance. Open (double-click) any entry to see the Sample Registration Screen shown in the next section. This is an example log. The user can establish as many logbooks as is necessary to organize the work of the lab. The content of the log is determined using the Customize View feature.

Sample Log Screen

6.1.2 Functions from the Log Menu

To accession a New Sample screen, click the New icon on the Tool bar. To view the details or edit the attributes of an existing sample, double-click the selected sample. Each sample has several folders to organize the entries associated with that sample. In addition to ordering tests on the patient's sample, the user can place a sample into inventory from the Locations screen, add sample comments on the Comments screen, and document unacceptable sample information on the Unacceptable screen.

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6.1.3 Sample Accessioning

To accession a new sample and order tests, press the ‘New’ (Sample) icon on the Tool bar. The New Sample screen is available for entering sample information, adding a new or selecting an existing patient, and ordering tests.

6.1.3.1 Sample Information

Complete the sample information on the top portion of the screen. The Sample Date defaults to today’s date. Change the date if necessary. Enter Sample Time (optional). Select a Specimen type and enter a Sample Count. Select an Ordering Physician. (This physician may be the same or different from the patient’s physician). Log date and time are filled automatically by the system. If the sample is to be listed on the DNA Worksheet, click the ‘Extract DNA?’ checkbox.

Shown below is the completed screen for an accessioned sample on a patient.

Sample Registration Screen

6.1.3.2 Patient Information

Before saving the sample, the patient or donor (provider of the sample) must be entered or selected from the database.

Select the Provider type (Patient, Donor, Proficiency) from the drop-down under the sample information. The screen provided is somewhat different for the various provider types. Other provider types available with additional modules are Panel Member, Cord, and Paternity.

NOTE: In order to build cases between patients and donors, the provider type must be properly selected.

6.1.3.2.1 Existing Patient

If the patient or donor is already in the database, enter the ID and press the tab key. The provider’s demographics will fill the fields. If the user questions the correct information on an existing patient, use the View Patient Information link to access a search screen. Enter the patient’s name to view similar patient records. Select the appropriate record.

6.1.3.2.2 New Patient

If the patient/donor has not been previously entered, enter the medical record or SSN. A message asks if the user would like to create a new patient. Press ‘Yes’ and the New Patient screen will appear for completion of all demographics. Press Save on the Patient Screen and Close to return to the Sample screen.
Press the Save button to save the patient. Press the Close button to return to the Sample Screen. Press the Save button on the Sample screen to save the sample and activate other Sample folders (Orders, Locations, Comments, and Unacceptable).

6.1.4 Orders

To order tests, click the Orders menu. Test orders are managed from the Orders folder. Use the hyperlinks across the top of the Order Information window to

- Add new tests,
- Edit previously ordered tests,
- Remove ordered tests,
- Cancel ordered tests,
- View tray data, and
- View the details of an order.

The status of each test can be viewed here. The status of each test changes as the test moves through the laboratory. Status designations are unassigned, assigned, completed, reviewed, and signed off.
6.1.4.1 Add Order

To order tests, click the ‘Add Order’ hyperlink. The screen opens to the ‘Individual Tests’ tab showing your list of test codes. Use the ‘Show’ frame to isolate Tests, Fees, or No Result codes. Click the ‘Batteries’ tab to order batteries. Double click the appropriate test or battery name. The selection will appear in the ‘Items to Order’ window below.

Tests can be ordered 1) to charge, 2) at no charge, 3) to tally repeat testing in workload, or 4) as prepaid. Select the billing status and the priority level prior to ordering a test or battery.

Selected tests and fees appear in the ‘Items to Order’ window at the bottom. Press the Order button to complete the order.

6.1.4.1.1 ‘Bill To’ Feature

If the ordered test is to be billed to someone other than the sample provider, highlight the ordered test and press the ‘Bill To’ button. Complete a choice of ‘Patient’, ‘Account’, or ‘Acquisition Code’.
6.1.4.1.2 ‘Crossmatch Test To’ Feature when ordering a Crossmatch Test

To result a crossmatch test, the patient/donor relationship must be established. Typically the crossmatch test(s) is ordered on the patient. The donor's records must be created before ordering the crossmatch on the patient.

When a crossmatch test is ordered, the system automatically provides the ‘Crossmatch To’ screen for entry of this information. The Crossmatch To screen can also be accessed from a previously selected crossmatch test by highlighting the test and pressing the ‘Crossmatch To’ button.

To use the Crossmatch To screen:
1. Create a new Case (press ‘Create New Case’) or use an existing one
2. Select a person who is already listed in a case or add a new person (press ‘Add Person to Case’).
3. Highlight the person and press ‘Select’.
4. The donor name will appear in the Crossmatch To column of the Order Tests screen.

Perform this function when ordering the test. If the donor’s record had not been created when the crossmatch test was ordered, return to the Orders screen of the patient after adding the donor record. Use the ‘Edit Order’ hyperlink to access the Crossmatch To screen. If the relationship has not be designated when the user is ready to enter results, the ‘Crossmatch Test To’ screen will appear at that time.

Crossmatch Test To Screen

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Close the Order Tests screen and view the tests on the Order Information list.

**Order Information Screen**

The Order Information list view is updated with the status of each test as it moves from ‘unassigned’, to ‘assigned’, to ‘completed’, to ‘reviewed’, and finally to ‘signed-off’. The date a test is billed can also be seen here.

### 6.1.4.2 Edit Orders

From the Order Information screen, highlight an existing test order and click Edit Order to make changes such as:

- **Billing Classification**
  - Charge status – change billing status for charge or no-charge
  - Bill To information – bill tests to another person, not the provider of the sample, to an account, or to an acquisition code.

- **Crossmatch Test To** – link a patient with a donor for crossmatch test resulting. This information can be completed at test ordering time or added/edited here.

- **Priority** – change priority codes

- **ICD-9 codes** – add/edit ICD-9 codes

**Maintain Order Screen**
6.1.4.3 Remove an Order

To remove an order from the system, highlight the order and press the ‘Remove Order’ hyperlink. No evidence of the order will remain in the system.

6.1.4.4 Cancel an Order

To cancel an order, highlight the order and press the ‘Cancel Order’ hyperlink. The status of the order will change to ‘canceled’. The order will be viewable from the patient’s order history screen with a status of ‘canceled’.

6.1.4.5 View Tray Data

View, add, edit, or remove tray information associated with a test.

6.1.4.6 View Order Details

To view the results of signed out tests from the Orders screen, press the ‘View Order’ hyperlink. The test’s results screen will appear.

6.1.5 Locations

To place a sample into inventory from the Sample Log menu, open the sample and select the Locations folder. The Sample Location list view will show the location of the sample if it has been placed into the inventory system.

The inventory location has been established in Administration. The user can enter samples manually or set the system to auto-fill the inventory.

6.1.5.1 Add to a Location

Press the ‘Add to a Location’ hyperlink to access the inventory system. Select a location from the ‘Location’ drop-down. Any content already in the container will appear.

- If the location is not ‘Auto-Fill’, the user can double-click any empty grid coordinate to add the sample to inventory.
- Or the user can press the ‘Add’ button next to the location drop-down. The system will add the sample to the next available coordinate. Press ‘Add’ multiple times to place multiple containers of this sample.
- If the system is set to Auto-fill, the user does not have to open the location screen for addition, only to view existing location.
6.1.5.2 Delete from Location

To delete from a location, highlight the sample on the Sample Location list and press the 'Delete from Location' hyperlink. Reply to the message.

6.1.6 Comments

To add sample comments, select the Comments folder. Add sample comments.

6.1.7 Unacceptable Samples

If the sample received does not meet your laboratory’s criteria of acceptability, use the ‘Unacceptable’ feature to document the issue. Click the Unacceptable folder to access the following screen.

If the sample problem can be resolved and the sample can be used for testing, check the ‘Resolution allows the return…’ box at the bottom of the screen. The tests ordered on this sample will move through the work management process. If the sample is not useable, complete the information for the quality assurance reporting.
6.1.8 Search for a Sample

The last samples accessioned are visible when the log list view opens. However, there may be a need to isolate particular samples that have been accessioned days/weeks/months ago. Use the Sample Search tool to locate these samples.

Press the binoculars on the tool bar to access the Find Sample Log screen for samples. The 'Search' tab provides fields for locating samples using either sample information, patient information or ordered test types. Enter the appropriate criteria and press the Find button. The log list view will list the selected samples.

If the Search tab does not provide an adequate result, use the ‘Advanced Search’ tab to create a specific search. Enter a new search each time or save previous searches for use later. Select a field name from the ‘Field Name’ drop down. Select a Condition. Enter a Value to satisfy the search. If the search is to be saved, press the ‘Save Search’ button. Then press the ‘Find’ button to filter the desired samples from the log of samples.

To return the log view to the full list of samples, press the ‘Refresh’ button on the tool bar.

Sample Search Screen

6.2 DNA Extraction

Press DNA Extraction from the Sample menu to access the DNA Extraction list view. The list will show all samples for which a check was placed in the box labeled ‘DNA Extraction?’ on the Sample screen. The provider’s name and ID will appear on the DNA extraction list as shown in the screen below.
To print a worksheet to use at the bench, highlight on the list view the samples to be tested. From the Tool bar, press the ‘Print’ icon to access the DNA Extraction Worklist report. Print the report and use it to record the amount and concentration of DNA on each sample on the list.

**DNA Extraction List View**

Return to this menu to enter the DNA Extraction values. Highlight single samples or use the Shift/Ctrl and highlight to select multiple samples. Enter DNA values and check ‘Save’ before closing the screen.

**DNA Extraction Data Entry Screen**

While the sample name is highlighted, press the ‘Place Sample into Inventory’ button and place the sample into inventory. The location and the entered DNA data will appear on the DNA Extraction screen of the provider screen.
7  The Work Management Menu

The Work Management menu provides the user with the ability to assign tests that have not been designated with default assignments during test setup in Administration. Tests can be assigned to Work Areas and to Technologists. With the Batch module, tests can be assigned to batches.

Work Management also includes workload calculations and turn around times for tests, work areas, and technologists.

7.1 Test Assignment

Click Test Assignment to view a list of Unassigned Tests. The list can be filtered based on Test Codes by choosing codes from the Test Types drop-down at the top of the screen. The list can be sorted in alphabetical order using Customize View. Alternatively, click the column headers to sort the list alphabetically by patient name or by test code.

To print an Unassigned Tests list, use the Print button on the Tool bar to access the ‘Unassigned Test Report’.

7.1.1 Assign Tests

Select the test(s) from the list and use the ‘Assign’ button on the Tool bar or right-click the mouse to select a Work Area, Technologist, or Batch. The assigned tests can then be viewed under the Results menu.

![Test Assignment Screen](image)

7.2 Test, Sample, and Patient Processes

These three menus all function with the same features, each one specific to the process type as labeled, Test, Sample, and Patient.

The Sample, Test, and Patient Process list views are all populated when a test, with a default process linked, is ordered. The list view below can be sorted using the filter drop-down at the top of the screen.
When a process has been completed for a sample (test/patient) or group of samples, highlight the group and right-click the mouse. Select Complete from the popup menu.

The system provides a choice of options for the next process in the sequence. The user has entered these choices in the Sample, Test, and Patient Dictionaries. The system has provided other choices.
This process continues until the Sample, Test or Patient tasks have been completed and the user selects <No Process> from the list.

7.3 Turn-Around-Time

Turn around time (TAT) can be calculated By Test, By Technologist, and By Work Area. For each of the three menus, the user selects the date range used to calculate the TAT for such test status periods as ‘ordered to completed’ and ‘ordered to signed out’. Press the Search button to complete the calculation and see a list of tests.

7.4 To Do List

Each user has his/her own To Do List. Add tasks to the list with due dates. Tasks that are overdue will show the date in red. Check the box next to completed tasks and remove them from the list.
8 The Results Menu

Tests that have been assigned and are ready for completion are organized under the Results menu. Tests that have been assigned incorrectly can be unassigned and returned to the Test Assignment menu for reassignment.

Tests are listed under the Results menu by
- My Work List,
- Work Area,
- Test,
- Patient,
- Batch, and
- Technologist.

The Tool bars and right-click menus operate the same on each screen. The user can ‘Add to My Worklist’, ‘Unassign’, and ‘Complete’ tests from this screen. Use the drop-down at the top of the screen to filter test codes, work areas, etc.

Tests appear in each of these areas if they have been assigned by default when the test was ordered or if they have been assigned under Work Management menu, Test Assignment submenu. Tests that are seen under ‘My Work List’ can also be seen under each of the other areas.

8.1 Test Result Completion

The process of entering test results is the same from each of the groupings, by Work Area, Test, etc.

1. Highlight one test or multiple tests of the same Test Type.
2. Press ‘Complete’ from the Tool bar or the right-click menu.
3. The field labels for the test are listed across the top of the screen. The patient’s name and ID are seen on the left of each row.
4. Enter test results across each row.
5. Reportable comments are unlimited in length and can be placed on a report.
6. Check the “Save data?” box and the “Results Complete?” if data entry is complete.
7. Press Save and Close to close the screen and move the completed tests on through the review cycle.
8. Two-step review tests will move on to the Review menu. One-step review tests will move on to the Sign Off menu.

Results Entry screen for a Class I Serological Test
Results Entry Screen for an antibody-screening test

Results Entry Screen for a Crossmatch test

For flow crossmatch components, enter the positive and negative control values before entering the patient values and the system will calculate the channel shift and the ratio, if those fields have been included as test components.
9 The Review and Sign Off Menus

Tests that have been completed under the Results menu move to either the Review or Sign Off. Both Review and Sign Off Menus operate the same way. Select like tests from the list and open single or multiple tests for review/sign off.

Tests can be signed off or returned to the bench for further testing. Save and Close from Sign Off to move the test results into the patient’s test history.

Tests Ready for Review

In addition to completing the review cycle for a test, the user can print final reports from the Sign Off Screen. Enter Reportable Comments in the appropriate field. Select the report to be printed from the drop-down presented in the Report field. Once the report is selected, use one of several choices for printing the report.

- Press Preview to use the Report Wizard and view the report on the screen. Determine if changes are to be made to the results or comments. Close the Preview screen. The selected report will remain in the Report field until selecting either the Print or the Save and Close button.
- Press the Print button to use the Report wizard. View the report and print. When the report is closed, the report name is removed from the Report field. Move to the next test.
- Complete the sign off process for all tests on the list and select a report for each test. Press the Save and Close button to print all the reports for the list, one after the next.

Tests Ready for Sign Off

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10 Inventory

The inventory system allows the user to place samples into storage locations of various sizes and shapes, all designed by the user. The system can track multiple sample types on the same specimen with a single accession number. In the Administration, the user sets up storage locations and designates the locations for storage of sera and DNA. Cells can be stored with the Cell Panel registry module and reagents can be stored with the Tray Management module. The functionality of the inventory is the same for all specimen types.

10.1 Serum Inventory or DNA Inventory

Select Sera from the Inventory menu. Select a location from the drop down at the top of the screen. Only locations that have been established for Sera in Administration will appear on the list. The list view of the contents for this location appears. The user can determine the order of the contents on the list by using the Customize fields and Sort functions. Click the ‘Show Grid’ box to view the contents in grid format. DNA Inventory has the same features as the Serum Inventory with only DNA locations available for selection.

Serum samples can be placed into an inventory system that is designed by the user to coincide with the physical inventory system used. The box size and naming scheme is user-defined. Samples are placed in one or more locations on the ‘Add Sample’ screen during accessioning or later, using the inventory menu. Use the ‘Find’ button on the Tool bar to locate desired samples.
11 Billing

All tests that have been ordered from the Sample menu with a billing instruction of ‘Charge’ will be placed in a billing queue. Periodically, the user will perform the billing function and remove tests from the queue, changing the billing status to ‘billed’. An invoice (report) can be printed and/or an electronic file can be exported, providing the billing information to the appropriate party.

Summary to steps in the billing process:
- Create billing template(s) – the query that filters the billable tests queue into desired test groupings
- Execute the billing template query
- Select the tests to be billed from the billing queue
- Set the status to billed
- Print an invoice or export a file
- Review billed tests by batch or by patient

11.1 Billing Template

The first step of the billing process is to create a billing template(s). The template is a query that filters tests in the billing queue based on the user’s needs for isolating groups of billable tests ordered by various hospitals or transplant programs, for patients, donors, projects, etc. Once the billing templates are created, the user will just execute the associated query periodically – daily, weekly, bi-weekly, monthly, etc. – retrieving any tests that fit the query.

To set up a billing template, complete the following steps. These steps assume you will print a billing report (invoice) and not export a file.
1. From the Billing menu, select Billing Templates. Press the New button on the Tool bar.
2. Provide a Name and a Description on the Billing Template screen. Save the new template.
3. Press the ‘Select Filter Criteria’ button on the Billing Template screen to open the Billing Template Filter screen below. Select from Patient, Sample, and Test fields to create a specific query.
   a. In this example, the user wishes to bill all renal patients from the various hospitals, under this physician. With the Patient radio button highlighted, select the Category field from the drop-down. Select the condition '=' and enter the value ‘renal’, placed in single quotes. Press the ‘Add to List’ button.
   b. Then select Hospital code in the Patient drop-down with the condition ‘IN’. Enter the values in multiple hospital codes in the format shown. Press the ‘Add to List’ button.
   c. For a Physician with duplicate entries that are different, use the LIKE condition. Add a wildcard symbol '%' if the LIKE value is a portion of the full value.
d. Use the Order date field under Test fields, to limit the time frame from the last billing batch to the date billing is done. This is useful for first of the month billing that is done a few days into the month.

Billing Template Filter Screen

```
Billing Template Filter

[Screen shot of the Billing Template Filter with various filter fields and conditions]
```

e. This template is shown to give examples of the format for the various filter conditions.

4. Create additional templates for each grouping of billable tests – this may be for each hospital for which you do business, or for each transplant program, etc.

11.2 Billing Batch

The next step in the billing process is to create a billing batch. Each time a group of tests is billed, a billing batch is created. The billing batch list view is seen when selecting the Billing folder under the Billing menu.

Billing Batch List View Screen

```
[Screen shot of the Billing Batch List View with a table showing billing batches]
```

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11.2.1 Billing Batch History

To view billing batch content, select the batch and double-click. This billing batch example contains one billed item.

**Billing Batch History Screen**

11.2.2 New Billing Batch

A new billing batch is created each time a group of tests is to be billed.

Complete the following steps:

1. From Billing Menu select the Billing folder. Press the New button on the Tool bar.
2. Select a billing template from the drop-down.

![New Billing Batch – Select a Template](image)

3. The list of tests in the billing queue that match the query of the template will be listed on the ‘New Billing’ screen. To complete the billing process, take the following steps:
   a. Complete the Billed Date and Billed By fields at the top of the screen. The Batch Number will be filled automatically with the next consecutive batch number.
   b. Select a Bill To Org. from the drop-down. This list is populated from the Hospital table. The contact name and address are those entered into the hospital record.
   c. Complete the Remit To information.
   d. Place a check next to each test to be billed, either by selecting individual tests from the list or by using the ‘Select/Deselect All’ check box at the bottom center of the screen.
New Billing Batch Screen

**e.** Press the Save button to save the billing batch. The message box alerts you that the selected tests/fees will be removed from the billing queue and the tests/fees will now have a status of ‘billed’. Select Yes.

**Message – Tests will be set to ‘Billed’ Status**

**f.** The message box informs the user of the batch number and the number of items that have been billed. Press the OK button.

**Batch Number Message**

**g.** Press the Close button on the New Billing screen to complete the billing process.

**h.** Press the Refresh button on the Tool bar to add the new batch to the list view.

**11.2.3 Print a billing report (invoice)**

The invoice report will list the items in the billing batch in a format designed by the user. All items in a batch may be totaled on a single invoice. Individual patients within a billing batch may be presented on individual invoices. The instructions for the content of the report are programmed into the invoice Crystal Report file.
To print an invoice, highlight the billing batch from the Batch list view. Press the Print button on the Tool bar and select the invoice report. Press the Print button on the print preview screen.

11.2.4 Exporting a billing batch

In addition to printing a billing report (invoice), the user can export the billing batch as a text file for use in another system. If exporting files, there are some additional steps required while setting up the billing template.

11.2.4.1 Setting up the fields to export

When establishing the billing template, the user must define some characteristics of the export file.

1. On the Billing Template screen, check the ‘Include Header in Export’ box if the export file is to contain the headers for the fields included in the file. Select a delimiter from the drop-down if the file is to be a delimited file.

2. The fields used for selecting tests from the billing queue are not necessarily the fields that would be required in the exported file. Press the Select Fields for Export button to select the appropriate fields for the file.

3. The Billing Template Export Fields screen provides for the selection of patient, sample, and test fields that can be included in the billing file. Below is an example of typical billing file content. Select the fields from the drop-down and press Add to List. Arrange the order using the Move Up and Move Down buttons. Press the Save button.
11.2.4.2 Exporting the billing file

Follow steps 3a. - 3f. in section 9.2.2 above to select tests and set them to a status of billed. After the billing batch has been saved, press the Export button on the bottom of the Billing screen. The Save As screen appears. Establish a directory for billing files and a logic for naming billing files. Save the billing file.

Save the Billing Export File

A message box provides a confirmation of the exported file.

11.2.5 Moving a test to a different billing batch

If the user includes a test in a billing batch incorrectly, the test(s) can be switched to a different batch. From the Billing screen, press the ‘Move to Different Batch’ button. The Select Billing Batch screen provides a choice of other batches. Highlight a different batch into which to move the incorrectly billed test. Press the Select button.

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Changing Billed Test to a Different Billing Batch

A message box informs the user of the change that is being made. The user would probably want to print a new billing invoice for each batch with the new information.

11.2.6 Credit a Billed Test

If a test has been billed and should not have been, the test can be credited. Open the billing batch that contains the incorrectly billed test. Highlight the test and right click the mouse. Select Credit Test. A message box informs the user that the test will be placed back in the billing queue.

Credit a Billed Test
11.3 Patient Billing History

In addition to reviewing each billing batch that may contain many patients, the user can search for billing information on individual patients. From the Billing menu, press the Billing By Patient folder. A Search for Patient button at the top of the screen provides a search screen to locate a patient. Select the desired patient and a list of tests/fees that have been billed on that patient appear on the list. If a correction is to be made, the user can open the billing batch for the desired test and move the test to a different billing batch.

Billing by Patient
12 Ad Hoc Query

The Ad Hoc Query tool is used for searching the database to answer questions the user may have, to provide information for reports, to send information electronically, etc. The most commonly used queries will require information from the Patient, Sample, and Test tables of the database. However, the user has all the tables in the database available for use in a query.

The process of query definition and execution is summarized here.
- Enter a name and description for the query.
- Select the table(s) from the database that contains the needed fields.
- If more than one table is selected, join each table with the appropriate field that is common between them.
- Enter filters to better define a field.
- Enter sort criteria to better display the query result.
- Save the query.
- Execute the query and review the outcome.

Queries that have been defined can be used many times. The list of defined queries can be viewed from the Ad Hoc Query Menu. Click the Ad Hoc Query folder. The queries in the example are typical of those a user might establish.

12.1 Query Definition

Following are the steps for defining a query.

1. From the Ad Hoc Query screen, press the New icon on the Tool bar. The New Query screen opens. On the Query Information tab, enter a Name and Description for the query. Select a delimiter for the file. Press the Save button.
2. On the Query Definition tab, press the Show Tables button on the far left of the Tool bar. A list of tables appears. Select and Add the desired table(s).
3. In this example, the Patient and Transplant Event tables are selected. Drag the windows to expand the table.

![Query Definition - Selected Tables and Selected Fields](image)

4. The system automatically joins the two tables.

5. Select the fields in each table that will provide the information needed. Place a check in the box next to the field. Select the fields in the order you wish to see them in the query result. In this example, the Patient table selections are Last Name, First Name, MRN, and Category. The Transplant History table selections are Donor Name, Organ, Donor Molecular Typing, Event and Event Date. The Event is filtered to provide only sensitizing events of the ‘Transplant’ type. Save the query.

12.2 Execute Query

For a new query or one that has been used before, the process is the same. Open the query screen and press the Execute Query button on the Tool bar (third button from the left). Change the screen to the Results tab to view the results.

![Query Results](image)
12.3 Export Query Results

Query results can be exported to a text file for use in another application such as Excel. Press the Export Results button on the Tool bar.

**Query Results - Export File**

The Save As window appears. Enter a name for the file. A location in the user’s directory can be allocated for query results. Open the file in Excel to print a report.

**Save Query Results**
The UNOS Module with UNet PRA Upload provides the user with tools to manage the group of patients who are awaiting transplant.

1. A record of user-entered patient transactions relative to their status on the transplant waiting list helps track each patient's availability for transplant.
2. A flag to designate a patient as listed for transplant provides a means of querying the database, either from the query tool or from batch accessioning and ordering, for this list of patients.
3. A list of patients who are to be placed on screening trays based on antibody level can be prepared.
4. A delimited file can be exported from the software specific to the requirements of the UNet web site for monthly PRA upload.

The UNOS Waitlist Module provides for download of the UNOS waitlist from that website with validation of the listed patients against the patients in the database who have been designated as UNOS listed.

### 13.1 Activation History

On the UNOS screen of the patient record, the user can record changes in the patient's status on the UNOS wait list. Press the Add Transaction button to add changes in status to the list seen here.

**UNOS Screen of Patient Record**

Changes made to all patients during a date range are seen from the UNOS Menu, Activation History submenu. Enter a date range and press the search button.

**Activation History for a Date Range**

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13.2 Generate PRA File

Periodically, patient antibody screening results are updated on the UNet web site, providing the Match Run process with a current PRA value when evaluating potential candidates for transplant. HistoTrac provides a file, created to match the UNet web site requirements, containing Peak and Current PRA values for each patient in the database who is designated as UNOS listed.

From the UNOS menu, select the Generate PRA File folder. Select a UNOS hospital from the drop-down at the top of the screen. The patients in the database with that hospital in the UNOS hospital field will appear on the screen.

List View of Patients for PRA File Export

Check the box to the left of the patients whose record is to be included in the export file. Use the ‘Select/Deselect All’ check box to select the entire list.

Press the Export button on the Tool bar. The Save As window appears. Name and save the file in a location on your directory designated for UNOS PRA uploads.

Go to the UNet web site and perform the upload function there.

13.3 ROP Tray

The ROP tray menu provides a filter mechanism to isolate patients whose Peak PRA values are greater than the value entered into the PRA Pct field. Use this tool to identify the patients who should be placed on screening trays for transplant.

List View of UNOS Listed Patients selected by PRA value
13.4 Wait List

The user will download the UNOS waitlist by performing that function from the institution’s password protected web page. Store the waitlist file in a directory location available from the HistoTrac software.

From the UNOS menu, select Wait List. Listed on the right will be any previously imported waitlist files.

List View of Wait List Files

To import a newly downloaded file, press the New icon on the Tool bar. A new Wait List screen appears. Complete the information at the top of the screen and save the record.

New Wait List Screen

1. Enter the Wait List number, the organ, the date of the wait list, and the date of import.
2. Save the record.
3. Press the browse button next to the File Name field to locate the downloaded Wait List file on your directory. Once the file is selected, the patients in the file will be listed in the window at the bottom.
4. Enter any comments in the Comments window.
5. Press the Validate button at the bottom of the screen. The system will compare the patients from the waitlist with those in the HistoTrac database. A progress bar is seen at the bottom.
6. Once the validation is complete, the colored icon to the left of the patient's name will designate whether a match was found between the listed patient and a patient in the database. Red indicates no match. Gold indicates the patient is in HistoTrac but is not flagged as UNOS listed. Yellow indicates the patient is flagged as UNOS listed.

7. To compare Waitlist patients with HistoTrac patients who are flagged as UNOS listed, check the 'Show UNOS Listed Patients?' checkbox. Those patients will be seen on the right.
8. To map a waitlist patient to a HistoTrac patient, highlight the matching patients from each list and press the 'Map To Wait List Patient' button. A message box will acknowledge the mapping. Mapping may be necessary if the patient’s name or ID information are different but the user can determine the records are for the same patient.
14 Administration Menu

The Administration menu is divided into dictionaries as listed in the sections below. Each dictionary contains the set up for the various tables that are related to the dictionary topic.

14.1 Patient Dictionary

The Patient Dictionary contains all the tables that are patient-related. Each active record will be seen in a drop-down on the Patient screen for each table. Double-click each record to view/edit record content. Each table allows for addition of new records. Click each folder on the list to see the list view. Use the New button on the Tool bar to create a new record.

### Patient Dictionary Menu Listing

<table>
<thead>
<tr>
<th>Work Management</th>
<th>Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patient Dictionary</td>
</tr>
<tr>
<td></td>
<td>Sample Dictionary</td>
</tr>
<tr>
<td></td>
<td>Test Dictionary</td>
</tr>
<tr>
<td></td>
<td>Tray Dictionary</td>
</tr>
<tr>
<td></td>
<td>Security Dictionary</td>
</tr>
<tr>
<td></td>
<td>Report Dictionary</td>
</tr>
</tbody>
</table>

### Physicians

When creating a Physician record, enter the Physician Code, then the First and Last Name for each physician who orders tests in your laboratory. Select a hospital from the drop-down. Complete the additional contact information, if desired. This table is used for the Ordering Physician (Sample screen) and the Physician (Patient screen) drop-downs.

Consider the following uses for the Physician's record:

- The Physician's name appears in the header on official reports.
- The Physician's hospital may appear on the header of official reports.
- The Physician code may be useful for billing purposes.
- Check the 'Receive Reports' checkbox if you are using an automated report queue. When a patient's test is signed out and a report goes to the print queue, a report will be printed that is intended for this physician.
- If billing the physician, complete the physician's Billing Code.
14.1.2 Hospitals

To create a Hospital record, enter the Hospital Code and Hospital Name for each hospital servicing the patients you test. Complete the additional contact information, if desired. The table is used to populate the Hospital drop-down on the Patient’s record.

Consider the following uses of the Hospital record.

- The Hospital Code may be useful for billing purposes.
- The Hospital Name may be used on patient reports.
- The Hospital Name may be useful for querying the database to obtain a listing of patients for this location.
- The Physician and Coordinator tables use the Hospital Name entry in a drop-down window.
- Check the ‘Receive Reports’ checkbox if you are using an automated report queue. When a patient’s test is signed out and a report goes to the print queue, a report will be printed that is intended for this hospital.

Hospital Record
14.1.3 Coordinators

When creating a Coordinator record, complete the Coordinator Code, then the First and Last Name of each coordinator associated with the patients for whom you do testing. Select the hospital from the drop-down. Complete the additional contact information, if desired. The table is used to populate the Coordinator drop-down on the patient record.

Consider the following uses for the Coordinator record.

- The Coordinator’s Name may appear in the header of a patient’s report.
- The Coordinator’s name and contact information may be used to provide sample mailers to patients.
- Check the ‘Receive Reports’ checkbox if you are using an automated report queue. When a patient’s test is signed out and a report goes to the print queue, a report will be printed that is intended for this coordinator.
- If billing the coordinator, complete the Billing Code.

Coordinator Record

14.1.4 Dialysis Centers

To create a new Dialysis Center record, enter a Center Code and Center Name. Complete the additional contact information, if desired. The table provides content to the Dialysis Center drop-down on the patient record.

Consider the following uses of the Dialysis Center table.

- Center name and contact information may be used to provide mailers for sample submission on Dialysis Center patients.
- If billing the Dialysis Center for services, complete the Billing Code.
14.1.5 Category Codes

Category describes an attribute of a patient or donor, often in relationship to the transplant program providing service. See the figure below to view examples of typical category entries. The table records populate the Category drop-down on the patient or donor record.

Consider the following uses of the Category field.
- The Category appears in the patient's header on final report.
- Category may be useful in billing.
- Category may be used when establishing queries for batch accessioning and batch ordering.
- Category may be used in querying of the database for patient data groups.

### Category Table

<table>
<thead>
<tr>
<th>Category Codes</th>
<th>Description</th>
<th>Active</th>
</tr>
</thead>
<tbody>
<tr>
<td>BM</td>
<td>Bone Marrow</td>
<td>Yes</td>
</tr>
<tr>
<td>Cataract</td>
<td>Cataract</td>
<td>Yes</td>
</tr>
<tr>
<td>Donor</td>
<td>Donor</td>
<td>Yes</td>
</tr>
<tr>
<td>Heart</td>
<td>Heart</td>
<td>Yes</td>
</tr>
<tr>
<td>Liver</td>
<td>Liver</td>
<td>Yes</td>
</tr>
<tr>
<td>Lung</td>
<td>Lung</td>
<td>Yes</td>
</tr>
<tr>
<td>MBD</td>
<td>MBD</td>
<td>Yes</td>
</tr>
<tr>
<td>Other</td>
<td>Other</td>
<td>Yes</td>
</tr>
<tr>
<td>Paternity</td>
<td>Paternity</td>
<td>Yes</td>
</tr>
<tr>
<td>Renal</td>
<td>Renal</td>
<td>Yes</td>
</tr>
<tr>
<td>RenalHeart</td>
<td>RenalHeart</td>
<td>Yes</td>
</tr>
<tr>
<td>Research</td>
<td>Research</td>
<td>Yes</td>
</tr>
<tr>
<td>Unrelated Donor</td>
<td>Unrelated Donor</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Consider the following uses of the Diagnosis field.
- The Diagnosis appears in the patient’s header on final report.
- Diagnosis may be useful in billing.
- Diagnosis may be used in querying of the database for patient data groups.

### Diagnosis Table

#### 14.1.7 Race Codes

The Race table contains entries that are appropriate to the ethnic groups for whom you provide service. Enter the Code and Description. Race is typically included in the patient header of official reports. The Race field is found on the patient and donor’s record.

#### 14.1.8 Gender Codes

The Gender table contains entries for Male, Female and Unknown. Enter the Code and Description. Gender is typically included in the patient header of official reports. The Gender field is found on patient and donor’s record.

#### 14.1.9 ABO Codes and Rhesus Codes

The ABO and the Rhesus tables contain entries that allow you to document the patient’s and donor’s Blood Group and Rh type. Enter the Code and Description. ABO and, in some cases, Rh are typically included in the patient’s or donor’s official reports. The ABO and Rh fields are found on the patient and donor’s record.

#### 14.1.10 Organ codes

The Organ table contains entries that describe the patient’s transplanted organ. The organ field is located on the Sensitizing event screen of the patient’s record. The example shows typical entries in the table.
14.1.11 Status Codes

The Status table contains entries that describe the patient or donor’s progression along the continuum of care. See the example below for typical entries in the table. The Status field is found on the patient or donor’s record.

Consider the following uses of the status field.
- The Status appears in the patient’s header on final report.
- Status may be useful in billing.
- Status may be used when establishing queries for batch accessioning and batch ordering.
- Status may be used in querying of the database for patient data groups.

Status Table

14.1.12 UNOS Hospital Codes

The UNOS Hospital table contains the initials used by the UNOS system to identify transplant centers. This field provides an additional hospital identifier, separate from the Hospital field. The patient may be cared for at one hospital and managed for transplant services at another.

Consider the following uses of the UNOS Hospital field.
- UNOS Hospital may be useful in billing.
- The UNOS Hospital may be used when querying the database for patient data groups.
- This field may be used to filter patient names for creating labels when sending sample mailers.

UNOS Hospital Table

14.1.13 UNOS Activation Codes

The UNOS screen on the patient’s record provides a feature for maintaining the current status of a patient on the UNOS waiting list. The Activation Code table provides a means of entry for the various activation status codes of the UNOS system. The table below provides examples of typical entries.
UNOS Activation Table

14.1.14 Acquisition Codes

The Acquisition Code is used in billing when a patient’s services are billed to a transplant program’s contract or budget code. The acquisition code is selected during the test ordering process using the ‘Bill To’ feature. Enter a Code and Description.

Acquisition Code Table

14.1.15 Patient Number Generator

The Patient Number Generator creates a unique consecutive number, used as a laboratory identifier for the patient or donor. The number is activated using a format code. More than one series of numbers can be used. If you service patients from different hospitals, create a numbering scheme for each location. The number can contain a code to differentiate the locations. This patient number generator may be useful if you do not consistently receive a Medical Record Number or SSN.

To use the Patient Number Generator:

- The Format Code is the code that is typed into the MRN/ID field. It calls forth the next number in that numbering series. If you are using a different numbering series for each hospital you service, enter a code such as ‘UMC’ for a numbering system for patients from University Medical Center. Alternatively, select a code that is easily and quickly typed such as ‘111’. This format code does not need to appear in the actual numbering sequence.
- Patient Number Format describes the format of the numbering sequence. Use letters and/or numbers to describe the format. In the UMC example, use the format ‘UMC999’ to have a patient number ‘UMC010’.
- The Last Sequence Number is the number preceding the first number of this series. If the series is to begin at ’1’, enter the value ‘0’. If the number is to begin at ‘UMC139901’, enter ‘139900’ in this field.
14.1.16 Insurance Carriers

If your center bills patients directly, you may need to use the Insurance Carrier table. Enter a Code and Description for each carrier. The table populates the Carrier Name drop-down on the Insurance screen of the patient record. Complete the remaining information about the patient’s coverage with the carrier on the patient’s insurance screen.

Insurance Carrier Table

Insurance Screen on the Patient Record
14.1.17 Surveys

Proficiency survey names are entered into the Survey table. When using the Proficiency Provider type on the Sample screen, the surveys entered into this table will be available for selection. The user would then enter only the sample number within the survey. Enter a Code and Description.

Entering surveys under the Survey Provider type helps keep queries of the database more specific. If a survey were entered as a Patient Provider type, queries requesting patient records will include survey records.

This table would be updated each year when a new survey subscription is activated. Names of surveys from previous year can be made inactive.

**Proficiency Survey Table**

14.1.18 Relationships

The Relationship table contains family or non-family descriptions of the relationship between the patient and a potential donor. The records in this table are available from the Relationship drop-down on the Case screen. The software may be provided with entries in the Relationship table. Add/edit/delete as needed.

**Relationship Table**

14.1.19 Case Numbering

Case numbering can be done several ways.

- A number can be provided automatically by the system (see set up in Tools/Options/Case.) The user can tell the system with which number to begin the sequence. No data entry on the Create Case screen is required to create the case number.
- The user may also enter a case number without regard for sequential numbers.
- A different number sequence, specific to case types, can be created using the Case Number Generator. Entry of the code on the Create Case screen will initiate the numbering sequence.

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To use the Case Number Generator:

- The Format Code is the code that is typed into the Case Number field on the Create Case screen, from the Patient record. It calls forth the next number in the numbering series associated with the code. If you are using a different numbering series for different types of cases, set up more than one format code. For example, enter a code such as ‘fam’, to number cases containing family members. Or use ‘dec’ for cases containing deceased donors. If creating only one numbering sequence, select a code that is easily and quickly typed such as ‘111’. This format code does not need to appear in the actual numbering sequence.
- Case Number Format describes the format of the numbering sequence. Use letters and/or numbers to describe the format. In the URD example, use the format ‘URD-99999’ to have a case number ‘URD-12345’.
- The Last Sequence Number is the number preceding the first number of this series. If the series is to begin at ‘1’, enter the value ‘0’. If the number is to begin at ‘URD-559’, enter ‘558’ in this field.

**Case Numbering Format**

```
Case Number Generator (0)
```

14.1.20 State Codes

The software is provided with a table containing the Code and Description for each state. The table can be modified to add or delete records.

14.1.21 Batch Method Codes

The Batch Test Management module provides a Batch Accession and Batch Ordering process. This process relies on creating queries to filter from the database a group of patients on who samples will be accessioned or tests ordered. One of the attributes on the patient record that will assist in querying to isolate groups of patients is the Batch Method. This field describes the testing method used for antibody screening for a given patient. Assign a Batch Method to a patient and use that field in the Batch Order query to isolate patients who are to be tested by that method.

Enter a Code and Description for each record in the table. The Batch Method drop-down is available on the Patient record, Specificity/Antigen folder.

**Batch Method Table**

14.1.22 Batch Period Codes

The Batch Test Management module provides a Batch Accession and Batch Ordering process. This process relies on creating queries to filter from the database a group of patients on who samples will be accessioned or tests ordered. One of the attributes on the patient record that will assist in querying to isolate groups of patients is the Batch Period Code.
Period. This field describes the frequency of antibody screening for a patient. Assign a Batch Period to a patient and use that field in the Batch Order query to isolate patients who are to be tested at that frequency.

Enter a Code and Description for each record in the table. The Batch Period drop-down is available on the Patient record, Specificity/Antigen folder.

### Batch Period Table

<table>
<thead>
<tr>
<th>Batch Period</th>
<th>Description</th>
<th>Active</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monthly</td>
<td>Monthly</td>
<td>Yes</td>
</tr>
<tr>
<td>Weekly</td>
<td>Weekly</td>
<td>Yes</td>
</tr>
</tbody>
</table>

#### 14.1.23 MulHos Codes

The MulHos code is used by laboratories with an ADT interface to a third party system.

#### 14.1.24 Patient Process Tracking

The Process Tracking Module provides a ‘Patient Process Template’. The user can define single or sequential work process steps that help manage the tasks performed on the patient that are not related to ordering and completing tests. The processes are activated during test set up and are managed from the Work Management Menu.

### Patient Process Table

<table>
<thead>
<tr>
<th>Process</th>
<th>Next Process</th>
<th>Active</th>
</tr>
</thead>
<tbody>
<tr>
<td>Create Patient Chart</td>
<td>Record ABG in HemTrac</td>
<td>Yes</td>
</tr>
<tr>
<td>Send ABG to Blood Bank</td>
<td>Record ABG in HemTrac</td>
<td>Yes</td>
</tr>
</tbody>
</table>

#### 14.1.25 Patient Auditing

The Patient Auditing table provides a listing of all the fields in the Patient Record. The user selects fields to be audited, documenting changes that have been made to the patient record.

To establish an audit trail of patient record fields, open each field in the table. Check the ‘Audit?’ checkbox. For all fields set to ‘Yes’, the system will record on the Patient Audit History screen of the patient record, all changes to the selected fields. If an ABO is changed from one Blood Group to another, the audit trail will record the initial entry, the new entry, the person who entered the change, and the date on which the change was made.
14.2 Sample Dictionary

The Sample Dictionary contains all tables related to handling samples. Each sub menu provides a list-view of the records in that table. Double-click any record to view the complete record. Press the New button on the Tool bar to create a new record.
14.2.1 Specimen Type

The Specimen Type table contains a listing of all types of tubes used for blood collection, as well as tissue and prepared samples. If a combination of tubes is often received, enter that combination, such as ACD and Clot. When accessioning a sample, the Specimen Type should be fully described with a single entry. There is a separate field for entering the number of each tube received.

Set a default value for this field under Tools/Options/Sample.

Specimen Type Listing

<table>
<thead>
<tr>
<th>Specimen Type Codes</th>
<th>Specimen</th>
<th>Description</th>
<th>Active</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACD</td>
<td>ACD</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>ACD+CLOT</td>
<td>ACD AND CLOT</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>CPRept</td>
<td>Lymphocyte Rept.</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>CL+EDTA-ACD</td>
<td>Clot + EDTA + ACD</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>EDTA</td>
<td>EDTA</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>HEP</td>
<td>Heparin</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NODES</td>
<td>Lymph Node</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>OTHER</td>
<td>OTHER</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>SWABS</td>
<td>Swab(s)</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

14.2.2 Log Book(s)

The logbook(s) used for viewing accessioned samples are set up here. Numbering system parameters are established here. The user will create the logbook appearance by using Customize View on the Sample log to select and sort the column headers.

The Sample Number Format field is used to create the accession number on each log. The number format for a current date, alpha characters, and numbers can be included in the accession number. Use DD (day), MM (month), and YY or YYYY (year) to code for the date. Use ‘9’ to code for a number. In the example, ‘99999’ codes for a 5-digit number.

Use the Last Number Field to begin the numbering sequence. If continuing a current numbering system, place the last number of the old system in this field. The system will begin the next accession number with the next number in the sequence.

Check the ‘Auto Number’ box so the system will automatically continue the numbering sequence.

If using the Label Printing module, establish the Printer and the Label Report by selecting from the drop-down. These fields will provide the appropriate choices if the label module has been installed. Establish the label and the label printer to be used for samples accessioned on each log, if using multiple logbooks. Check the ‘Generate Label on Order’ checkbox to activate this function.

When printing labels, the user has the option of setting the number of labels by default or by entering the number at run time.

- To set the number by default, select a number in the ‘Number of Labels’ field. Each time a new sample is saved, labels will print according to this instruction.
- To enter the number when printing, check the ‘Prompt when Printing Label’ checkbox. The printer selection screen will appear each time a new sample is saved. The user will enter the number of labels at that time.
If multiple logbooks are used, the user can determine the default logbook (that which appears when the Sample Menu/Log submenu is first accessed) by selection on the System menu under Tools/Options/Sample.

14.2.3 Storage Locations

Inventory Storage Locations are established by creating a ‘container’ for the placement of serum, DNA, reagents, and cells. Serum and DNA storage are available with the Core software. Reagent storage is available with the Tray Management module. Cell storage is available with the Cell/DNA Panel Registry and Inventory.

The example shows a list view of the various inventory locations.

To establish a location, press the New button on the Tool bar. Enter a location description that will provide adequate information to identify the freezer, rack, and box. The ‘# of Rows’ and ‘# of Cols’ fields will create the internal map of the container.

The system will track as many as three samples within one grid inside the container. Depending on the tube size in use, place a number in the ‘# Per Space’. Check the appropriate box to connect this location to the Serum, DNA, Reagent, or Cell inventory.

The Auto-Fill checkbox is used when the system is to locate the next available grid location in the next box, based on an ‘auto-fill order’ number. Enter a number in the Auto-Fill Order field for each location in inventory, with ‘1’ being the first location to be filled, then ‘2’, then ‘3’, etc., until all the locations have an order number. The system will identify the first location where there is an empty grid.

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14.2.4 Unacceptable Reasons

On the Sample screen, Unacceptable folder, the user can enter the reasons why a sample that has been received does not meet the laboratory's standards for sample acceptance. This table populates the drop-down on the Unacceptable screen. See below.

**Unacceptable Reasons Listing**

<table>
<thead>
<tr>
<th>Unacceptable Reason</th>
<th>Description</th>
<th>Active</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broken</td>
<td>Broken in Transit</td>
<td>Yes</td>
</tr>
<tr>
<td>Cancelled</td>
<td>Cancelled Test</td>
<td>Yes</td>
</tr>
<tr>
<td>Chilled</td>
<td>Chilled</td>
<td>Yes</td>
</tr>
<tr>
<td>Damaged</td>
<td>Damaged</td>
<td>Yes</td>
</tr>
<tr>
<td>Incorrect Requisition</td>
<td>Incorrect Requisition</td>
<td>Yes</td>
</tr>
<tr>
<td>Name Discrepancy</td>
<td>Name Discrepancy</td>
<td>Yes</td>
</tr>
<tr>
<td>No Date</td>
<td>No Date</td>
<td>Yes</td>
</tr>
<tr>
<td>No ID/IS#</td>
<td>No ID/IS#</td>
<td>Yes</td>
</tr>
<tr>
<td>No Label</td>
<td>Tubular not labeled</td>
<td>Yes</td>
</tr>
<tr>
<td>No Requisition</td>
<td>No Requisition</td>
<td>Yes</td>
</tr>
<tr>
<td>No Sample</td>
<td>No Sample</td>
<td>Yes</td>
</tr>
<tr>
<td>Out</td>
<td>Out</td>
<td>Yes</td>
</tr>
<tr>
<td>Too Old</td>
<td>Sample Too Old</td>
<td>Yes</td>
</tr>
<tr>
<td>Wrong Tube</td>
<td>Wrong Tube</td>
<td>Yes</td>
</tr>
<tr>
<td>Wrong ID</td>
<td>Wrong ID</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Unacceptable Sample Screen**

14.2.5 Resolution Reason

On the Sample screen, Unacceptable folder, the user can enter the Planned Resolution to the unacceptable sample event. This table populates the drop-down on the Unacceptable screen. See below.

**Resolution Reason Listing**

<table>
<thead>
<tr>
<th>Resolution Reason</th>
<th>Description</th>
<th>Active</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancelled</td>
<td>Cancelled Test</td>
<td>Yes</td>
</tr>
<tr>
<td>Discontinued</td>
<td>Discontinued specimen</td>
<td>Yes</td>
</tr>
<tr>
<td>Requested new spec</td>
<td>Requested new spec</td>
<td>Yes</td>
</tr>
<tr>
<td>Requested required</td>
<td>Requested required</td>
<td>Yes</td>
</tr>
</tbody>
</table>
14.2.6 Received From

On the Sample screen, Unacceptable folder, the user can enter the location from which the unacceptable sample was received. This table populates the drop-down on the Unacceptable screen. See below.

Received From Listing

<table>
<thead>
<tr>
<th>Received From</th>
<th>Description</th>
<th>Active</th>
</tr>
</thead>
<tbody>
<tr>
<td>APS</td>
<td>Advanced Pathology Services</td>
<td>Yes</td>
</tr>
<tr>
<td>NHLBI</td>
<td>National Institutes of Health</td>
<td>Yes</td>
</tr>
<tr>
<td>MDACC</td>
<td>MD Anderson Cancer Center</td>
<td>Yes</td>
</tr>
<tr>
<td>MSKCC</td>
<td>Memorial Sloan Kettering Cancer</td>
<td>Yes</td>
</tr>
<tr>
<td>SFGH</td>
<td>Stanford University Medical</td>
<td>Yes</td>
</tr>
<tr>
<td>NYU</td>
<td>New York University</td>
<td>No</td>
</tr>
<tr>
<td>SSMIC</td>
<td>Saint Louis Medical Center</td>
<td>Yes</td>
</tr>
<tr>
<td>UHONU</td>
<td>University Hospital</td>
<td>Yes</td>
</tr>
<tr>
<td>UTMC</td>
<td>University of Texas Medical</td>
<td>Yes</td>
</tr>
</tbody>
</table>

14.2.7 Batch Accession Rules

Using Batch Accession Rules (with the Batch Test Management Module), samples can be accessioned (and tests ordered) quickly on groups of patients. Establish a Batch Accessioning Rule that identifies a group of patients, based on a set of descriptive qualifiers. These qualifiers select patients based on such database fields as category, status, physician, coordinator, hospital, ABO, etc.
When setting up the rules, establish the qualifiers that will provide a list of patients who are likely to send samples at the same time.

To create a Batch Accessioning Rule, click New on the Tool bar to open a new Accession Rule screen. Complete the name, description and check the Active checkbox. Under Field Name select a field such as Category. Select the Condition such as 'is (equals)'. The Category table records are available in the Value drop-down. In the example below, select Renal. Use the same process to add other search criteria to the rule query. Save the rule.

The rule is established in Administration and executed on the Sample Menu, Batch Accessioning screen. Execute a selected rule. Check patients who names are on the list, who have new samples to accession. If the selected patients are to have the same test ordered, the test ordering screen is available. Further instructions for using the Batch Accessioning Rule are found in the Batch Test Management section of this manual.
14.2.8 Batch Ordering Rules

Using Batch Ordering Rules (with the Batch Test Management Module), patients (and associated samples) are selected from the database so tests can be ordered quickly. Establishing a Batch Ordering Rule identifies a group of patients, based on a set of descriptive qualifiers. These qualifiers select patients based on such database fields as category, status, Batch Method, Batch Period, PRA values for Class I and Class II, and Sample Date range.

When setting up the rules, establish the qualifiers that will group providers who are to be tested using a particular test method. When using the rule on the Batch Ordering Screen, the selected patients’ current sample will be available for test ordering.

The rule is established in Administration and executed on the Sample Menu, Batch Ordering screen. Execute a selected rule. Check patients who names are on the list on whom you wish to order the same test(s). Further instructions for using the Batch Ordering Rule are found in the Batch Test Management section of this manual.
14.2.9 Sample Process Template

The Process Tracking Module provides a ‘Sample Process Template’. The user can define single or sequential work process steps that help manage the tasks performed on the sample that are part of the testing process but that are not related to ordering and completing tests. Examples of Sample Processes would be PCR amplification, primer selection, and gel loading. The processes are set up during test definition, activated when a sample is accessioned, and are managed from the Work Management Menu.

Sample Process Tracking Listing

14.2.10 Sample Auditing

The Sample Auditing table provides a listing of all the fields in the Sample Record. The user selects fields to be audited, documenting changes that have been made to the sample record.

To establish an audit trail of sample record fields, open each field in the table. Check the ‘Audit?’ checkbox. For all fields set to ‘Yes’, the system will record on the Patient Audit History screen of the patient record, all changes to the selected fields. For example, if a Sample Date is changed, the audit trail will record the initial entry, the new entry, the person who entered the change, and the date on which the change was made.
Sample Auditing Field Listing

<table>
<thead>
<tr>
<th>Field Items</th>
<th>Field</th>
<th>Audit?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen Type Codes</td>
<td>A302 Amount</td>
<td>Yes</td>
</tr>
<tr>
<td>Log Blocks</td>
<td>A303 Amount</td>
<td>Yes</td>
</tr>
<tr>
<td>Storage Locations</td>
<td>Allow Failure?</td>
<td>No</td>
</tr>
<tr>
<td>Unacceptable Reason</td>
<td>Classification Code</td>
<td>No</td>
</tr>
<tr>
<td>Resolution Reason</td>
<td>Contacted Name</td>
<td>No</td>
</tr>
<tr>
<td>Received From</td>
<td>Contacted Phone Number</td>
<td>No</td>
</tr>
<tr>
<td>Batch Accession Rules</td>
<td>DNA Concentration Amount</td>
<td>Yes</td>
</tr>
<tr>
<td>Batch Ordering Rules</td>
<td>DNA Extract Date</td>
<td>Yes</td>
</tr>
<tr>
<td>Sample Procedure Template</td>
<td>DNA Value</td>
<td>No</td>
</tr>
<tr>
<td>Sample Auditing</td>
<td>DNA Value Amount</td>
<td>No</td>
</tr>
<tr>
<td>Test Dictionary</td>
<td>Extracted?</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>High FRA</td>
<td>No</td>
</tr>
</tbody>
</table>

Sample Audit History – Patient Record

<table>
<thead>
<tr>
<th>Type</th>
<th>Field</th>
<th>Category</th>
<th>Old Value</th>
<th>New Value</th>
<th>Date</th>
<th>Sample #</th>
<th>Test Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Update</td>
<td>ABO</td>
<td>Patient</td>
<td></td>
<td>0</td>
<td>A</td>
<td>04/21/2003</td>
<td></td>
</tr>
<tr>
<td>Update</td>
<td>Sample Data</td>
<td>Sample</td>
<td>4/16/2003</td>
<td>4/14/2003</td>
<td>04/21/2003</td>
<td>03421.00574</td>
<td></td>
</tr>
</tbody>
</table>

14.3 Test Dictionary

The Test Dictionary is the location of all test definitions, batteries, result-field definition, allele tables, etc. See the example below for a list of tables found in the Test Dictionary.

Test Dictionary List View
14.3.1 Test Definitions

All Test Definitions are user-defined. The user will establish the name and test classification, billing criteria and attributes, work management alignments, and the fields available for test resulting. Some printing parameters are set if the user has the report scheduler called Report Manager.

In the example below, ‘Test Definitions’ is highlighted on the submenu and the list view shows a list of all tests. Double-click a test on the list to see the Test Definition screen. To add a new test, click the New icon on the Tool bar.

Test Definition List View

To create a test definition, begin with a new Test Definition screen.

- Complete the Test Type Code (used on the Test Ordering screen as an abbreviated test name.)
- Enter a Description (may be used on the official report).
- The use of Test Classification provides the appropriate fields for setting up serology, molecular, antibody, crossmatch, and other tests. Selection of the Tests Classification (upper right) populates the ‘Available Fields’ window (bottom right).
- Select a Default Work Assignment area (if desired).
- Check the Work Area that performs the test (required).
- Include billing information in the Charge Amount, Work Units and Bill Code fields.
- If using the Report Manager, select the report to associate with this test on sign off.
- To select fields for results entry, choose from the Available Fields window on the right. Double click to add to the list in the Results window on the left.
- Arrange the fields in the order needed for resulting. Highlight the item to be moved. Use the Up and Down buttons on the far left to arrange the list.
- Check the ‘Include in Result’ box for all fields that should be seen on the Test History list view(s) under a summary column called Results.
- If a field should have a default value, either choose it from the drop-down or manually enter the default value.
Test Definition for an Antibody Test

Test Definition for a Serology Typing Test

Test Definition for a Molecular Typing Test

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Test Definition for STR Test (Microsatellite Testing Module)

Consider the use of the following features of the test definitions.

- Tested Date is available as a user entered field.
- The available fields for each classification can be supplemented with User-defined fields. These fields are entered under the User Defined Test Fields of the Test Dictionary.
- One or more CPT codes can be associated with each test.
- Reportable comments can be added at the test level. The Reportable Comments can be added/edited during the test result/review process. The report to be used can be programmed to include this field. The user can therefore enter reportable comments at the test level and send the test result on sign out to an automated report queue (using the Report Manager). The Reportable comments field has an unlimited size.
- Using automated reporting (Report Manager), a default report associated with each test can be selected during test setup. When the user signs out a test result, the default report will automatically move to the report queue.
- A label report and selected printer can be associated with a test (different from labels associated with samples accessioned on a logbook.)
- Results can be sent or not sent to an interface using the ‘Send Results through Interface’ checkbox. This feature allows some test results to be reported manually while some are sent through a results interface to another hospital system.
- The Default Test Process button is used to activate user-defined tasks or activities that are routinely performed during the testing process. This feature is available with the Process Management for Patients, Samples, and Tests Module.) Select a task from this list and it will appear on a Test or Sample Process Worksheet each time this test is ordered. The processes can be linked such that one process automatically follows another.
• Crossmatch tests are set up with components—line items that are the equivalent of test battery components. This component approach allows the user to set up a single/few crossmatch tests for easy results entry and a simplified billing process. Add component names until the list fully describes the crossmatch test. The column headers in this example are the fields that were selected on the Test Definition screen. Many of the fields can be defaulted to speed results entry.

Test Definition for a Crossmatch Test

14.3.2 Test Batteries

Test batteries are groups of tests or fees. The use of a battery makes test ordering faster. If groups of tests are often ordered at the same time, place the test/fees into batteries. All tests in the battery are ordered by selecting just the battery.

Test Battery List View

To create a new battery, press the New button on the Tool bar to open a new Battery screen. The Test Type codes of all defined tests are available for selection. After selecting the tests to be included, check the ‘Charge’ box if the tests within the battery are to be sent to the billing queue. If some, but not all, tests in the battery are to be charged, check only the appropriate tests.

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Test Battery for group of Serology Tests

If the charge for the battery is different from the total of the included tests, set up a fee that will charge for the battery content. Do not check the ‘Charge’ box for each test, only for the fee.

Battery for Tests and a Fee

14.3.3 User-defined Test Fields

For each test classification, the user can add fields, not provided in the Available Fields list. There may be fields that are special to one lab’s needs that are not routine choices for a particular test. This example adds a user-defined field to the STR classification.

Definition for a User-defined Test Field

Information contained in this document is confidential to SystemLink, Inc and its principals and may not be used without permission.
Consider the following when setting up a user-defined field.

- The Field Name is the name used in the database and cannot contain spaces if using more than one word. Example 'SpecimenType'.
- The Label Name is the value that will be listed in the Available Fields list on Test Definition. Therefore, it will be used when resulting the test or viewing it in test history.
- Data Type will typically be ‘String’. Other choices are ‘Numeric’ and ‘Boolean’.
- Test Class is the classification into which this new field will be listed. Choices are Antibody, Crossmatch, Serological, Molecular, and Other when using the Core software. STR, Red Cell, and Infectious Disease, are available with the respective modules.
- Max Length is the size of the field for entry of data. Select a value greater than your expected typical entries.
- Default Value will fill the field automatically. The user will be able to change the default when entering results.

14.3.4 Test Priority

Test priority assists the user in identifying tests whose completion is urgent compared to routine. The Test Priority table provides a numeric scale from 1 to 10 with a descriptive word and color associated with each. Test Priority is chosen on the Test Order screen. The value can be defaulted under System menu Tools/Options/Test.

14.3.5 Test Method

Test Method can be associated with each test as a user-entered field during results entry. The field is chosen on Test Definition. The default values for selection are those in the Test Method table.

14.3.6 Test Process Tracking

'Test Process Template' provides the user with a tool to define single or sequential work process steps that help manage the tasks performed on tests that are not related to ordering or completing tests. These processes are activated during test setup and managed from the Work Management menu.
14.3.7 Transplant Status Codes

Transplant Status codes are associated with tests to define the timing of test ordering. Example entries would be 'Pre' and 'Post'.

14.3.8 Serological Alleles

Serological Allele tables for HLA loci A, B, Bw, Cw, DR, DRw, and DQ contain the identified alleles for each locus. The tables are provided with the software. The user can further manage content. The tables are connected to each locus during entry, review, sign off, and editing of values associated with serological typing tests for validation of proper allele selection for each locus.

14.3.9 Molecular Allele Tables

Molecular Allele tables for HLA loci A, B, Bw, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1, and DPB1 contain the identified alleles for each locus. The tables are provided with the software. The user can further manage content. The tables are connected to each locus during entry, review, sign off, and editing of values associated with molecular typing tests for validation of proper allele selection for each locus.

The user can enter serological equivalents for each molecular allele. This is particularly useful for reporting equivalents of molecular testing to be compatible with requirements for solid organ transplantation.

Molecular Allele Record with Serological Equivalent

14.3.10 Antibody Test codes

Two tables provide choices for data entry for antibody screening tests. These tables are available for selection of values during result, review, sign off, and editing of antibody-screening tests.

- Antibody Cell Type Codes table contains values that describe the class of marker on the cell surface for which the antibody screen identifies associated antibodies. Examples would be 'T', 'B', 'Class I', and 'Class II'.

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14.3.11 Crossmatch Test Codes

Four tables provide choices for data entry for crossmatch tests. These tables are available for selection of values during result, review, sign off, and editing of crossmatch test.

- Crossmatch Cell Type Codes table contains values, similar to the Antibody Cell Type Codes, that describe the class of marker on the cell surface for which an antibody is detected in a crossmatch test. Examples would be 'T', 'B', 'Class I', and 'Class II'.
- Crossmatch Treatment Codes table contains various treatments for sera used in crossmatches to differentiate antibody reactivity patterns. Examples would be DTT, platelet absorption, IgG and IgM labels, heat treatment, etc.
- Crossmatch Temperature Codes table contains temperatures at which crossmatch tests are performed.
- Crossmatch Result Codes table contains values used for resulting a crossmatch test. Examples would be positive, negative, compatible, incompatible, etc.

14.3.12 STR DNA Locus

The STR DNA Locus table allows the user of the Microsatellite Testing module to enter the identification of the DNA locus markers used for STR testing. The table includes the DNA locus and its chromosome. The values are available when creating a test definition for the test classification STR. The user has other appropriate fields available for test definition – those that apply to engraftment or to paternity testing.

**Example of STR DNA Locus Table Entries**

<table>
<thead>
<tr>
<th>STR DNA Locus</th>
<th>DNA Locus</th>
<th>Chromosome</th>
<th>Active</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Process Template</td>
<td>D1S1800</td>
<td>2</td>
<td>Yes</td>
</tr>
<tr>
<td>Transplant Status Codes</td>
<td>D1S1800</td>
<td>2</td>
<td>Yes</td>
</tr>
<tr>
<td>Serology A Allele</td>
<td>D1S1800</td>
<td>2</td>
<td>Yes</td>
</tr>
<tr>
<td>Serology B Allele</td>
<td>D1S1800</td>
<td>2</td>
<td>Yes</td>
</tr>
<tr>
<td>Serology C Allele</td>
<td>D1S1800</td>
<td>2</td>
<td>Yes</td>
</tr>
<tr>
<td>Serology D Allele</td>
<td>D1S1800</td>
<td>2</td>
<td>Yes</td>
</tr>
<tr>
<td>Serology E Allele</td>
<td>D1S1800</td>
<td>2</td>
<td>Yes</td>
</tr>
<tr>
<td>Serology F Allele</td>
<td>D1S1800</td>
<td>2</td>
<td>Yes</td>
</tr>
<tr>
<td>Molecular A Allele</td>
<td>D1S1800</td>
<td>2</td>
<td>Yes</td>
</tr>
<tr>
<td>Molecular B Allele</td>
<td>D1S1800</td>
<td>2</td>
<td>Yes</td>
</tr>
</tbody>
</table>

14.3.13 Red Cell Test Codes

The patient record provides a place for entry of ABO and Rh. These fields are data fields, not results of ordered tests. The ABO and Rh table provide valid blood groups for your laboratory.

If the Red Cell Typing Module is in use with your system, an additional table, Red Cell Antibody Results, is provided. These tables are available for selection of values during result, review, sign off, and editing of Red Cell tests.

- Red Cell ABO Result Codes
- Red Cell Rh Result Codes
- Red Cell Antibody Result Codes

14.3.14 Infectious Disease Test Codes

Two tables provide choices for data entry for Infectious Disease tests with the Infectious Disease Module.

- Infectious Disease Result Codes table contains values used for resulting infectious disease tests, usually by an ELISA methodology. Examples would be Reactive, Non-Reactive, etc.
- Infectious Disease Range Codes table contains values that describe the Normal Range for each of several types of infectious disease tests. Examples would be < Cutoff, > Cutoff, etc.
14.3.15 CPT Codes

A CPT code table is included. Enter CPT codes in the table. The table content is available for selection of single or multiple codes during test definition.

14.3.16 Test Auditing

The Test Auditing table provides a listing of all the fields in the Test Record. The user selects fields to be audited, documenting changes that have been made to the test record.

To establish an audit trail of test record fields, open each field in the table. Check the ‘Audit?’ checkbox. For all fields set to ‘Yes’, the system will record on the Patient Audit History screen of the patient record, all changes to the selected fields. For example, if a test result of %PRA is changed, the audit trail will record the initial entry, the new entry, the person who entered the change, and the date on which the change was made.

**Test Auditing List**

<table>
<thead>
<tr>
<th>Patient Work Management</th>
<th>Test Auditing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Field Name</td>
</tr>
<tr>
<td>Results</td>
<td>Test Definitions</td>
</tr>
<tr>
<td></td>
<td>Test Batteries</td>
</tr>
<tr>
<td></td>
<td>User Defined Test Fields</td>
</tr>
<tr>
<td></td>
<td>Test Priority Codes</td>
</tr>
<tr>
<td></td>
<td>Test Method Codes</td>
</tr>
<tr>
<td></td>
<td>Test Process Template</td>
</tr>
<tr>
<td></td>
<td>Transplant Status Codes</td>
</tr>
<tr>
<td></td>
<td>Serology A Alleles</td>
</tr>
<tr>
<td></td>
<td>Serology B Alleles</td>
</tr>
<tr>
<td></td>
<td>Serology C Alleles</td>
</tr>
<tr>
<td></td>
<td>Serology DR Alleles</td>
</tr>
<tr>
<td></td>
<td>Serology Ds Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular A Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular B Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular C Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRI A Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRI B Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS A Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS B Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS C Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS D Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS DR Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS Ds Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS A Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS B Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS C Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS D Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS DR Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS Ds Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS A Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS B Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS C Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS D Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS DR Alleles</td>
</tr>
<tr>
<td></td>
<td>Molecular CRIS Ds Alleles</td>
</tr>
<tr>
<td></td>
<td>Antibody Type Codes</td>
</tr>
<tr>
<td></td>
<td>Antibody Result Codes</td>
</tr>
<tr>
<td></td>
<td>Crossmatch Cell Type Codes</td>
</tr>
<tr>
<td></td>
<td>Crossmatch Treatment Codes</td>
</tr>
<tr>
<td></td>
<td>Crossmatch Temperature Codes</td>
</tr>
<tr>
<td></td>
<td>Crossmatch Result Codes</td>
</tr>
<tr>
<td></td>
<td>CPT Codes</td>
</tr>
<tr>
<td></td>
<td>Test Addres</td>
</tr>
</tbody>
</table>

**Test Auditing History**

<table>
<thead>
<tr>
<th>Type</th>
<th>Field</th>
<th>Category</th>
<th>New Value</th>
<th>Old Value</th>
<th>Audit Date</th>
<th>Sample ID</th>
<th>Test Type</th>
<th>Co</th>
</tr>
</thead>
<tbody>
<tr>
<td>Update</td>
<td>ABO</td>
<td>Patient</td>
<td>O</td>
<td>A</td>
<td>04/21/2003</td>
<td>00421-00574</td>
<td>STA1 PRA</td>
<td>S</td>
</tr>
<tr>
<td>Update</td>
<td>Sample D.</td>
<td>Sample</td>
<td>4/15/2003</td>
<td>4/14/2003</td>
<td>04/21/2003</td>
<td>00421-00574</td>
<td>STA1 PRA</td>
<td>S</td>
</tr>
<tr>
<td>Update</td>
<td>PRA %</td>
<td>Test</td>
<td>50</td>
<td>35</td>
<td>04/21/2003</td>
<td>00421-00574</td>
<td>STA1 PRA</td>
<td>S</td>
</tr>
<tr>
<td>Update</td>
<td>Total Ptns</td>
<td>Test</td>
<td>50</td>
<td>35</td>
<td>04/21/2003</td>
<td>00421-00574</td>
<td>STA1 PRA</td>
<td>S</td>
</tr>
</tbody>
</table>

14.4 Tray Dictionary

The Tray Dictionary is provided with the Tray Management module. It contains the tables needed to create tray maps, using either samples or reagents.

The user would create trays containing samples with ordered tests using the tray wizard under the Sample Menu. All other trays using patient samples, such as cadaver screening trays, can be built in the Trays submenu.
14.4.1 Trays

Tray maps or tray definitions require placement of samples or reagents into well locations on a tray. There are two steps to creating a tray map 1) configuring the tray, and 2) adding content to the tray.

14.4.1.1 Tray configuration

To configure a tray:

- Enter a Tray Name.
- Select a Tray Size.
- Check the ‘Left to Right View?’ to display a portrait or landscape view of the tray. The example below is landscape, most often used for 96-well trays.
- Select a Tray Type. The choices in the drop-down below are provided from the Tray Type Codes table, with the exception of Template, provided in the software.
- Select Tray Type = Template if this tray is to be used for copying to other tray names.
- Check the ‘Active?’ checkbox to make this tray available in Tray drop-downs.
- Enter a Lot Number, if appropriate.
- Enter an Expiration Date, if appropriate.
- Save the tray.

The next step of configuration is to identify the order in which content is to be loaded. To set the population order, continue with the following.

- Press the Set Population Order button.
- In the beginning well, right click the mouse. Choose Start Recording from the popup menu.
- Click the mouse in each well consecutively, in the order that samples are to be placed on the tray. The example provided shows the sample order moving down paired columns.
- Use the other choices in the popup menu to complete the configuration.
- To return to the view for loading samples, press the Show Well Contents button.
Set Population Order

Each tray map can be configured individually. However, if you use the same configuration for multiple trays, establish a template that can be copied to other tray names. Set the population order (as described above) and place controls in selected wells. Templates can also be used in the Tray Wizard when creating trays from a batch of ordered tests.

To configure a template with controls:
- Use the Search screen for Reagent to list the content of the Control table.
- Double-click each control. The controls will move to the wells in order set by the Population Order.
- Once all controls are added, save the tray. It is ready to use as a Template for other trays.

Once the tray is copied and renamed, add samples and reagents.
14.4.1.2 Tray Content

Use with the Samples search mechanism or the Reagent search mechanism to list selected content for placement on a tray. Use the filter, condition, and value fields to search for desired samples or reagents. Double-click each to place on the tray map. Load all samples until the tray is complete. Save the tray.

Search for Sample to load tray

14.4.2 Tray Types

Tray Types table provides choices when creating the tray definition on the Trays screen. The table content populates the Tray Types field on the Tray screen. Add tray types as seen in the example below.

Tray Types List View

14.4.3 Tray Groups

Tray Groups are useful in grouping trays that are used together – most often cadaveric screening trays for a particular blood group.
Tray Groups

14.4.4 Dilution Codes

The Dilution table codes are available on the Tray screen when adding content to a tray.

14.4.5 Reagents tables

The Tray Management Module provides five tables for the addition of reagent records – Control, Antiserum, Antibody, Primer, and Probe. Each table’s contents are available from the Reagent Search screen when creating a tray.

14.5 Security Dictionary

The Security Dictionary provides User, Role, and Work Area tables. Once User records are created and each user has been linked to a Role and Work Area(s), the Security menu establishes menu permissions for each user.

14.5.1 User menu

The user profile contains Name and Phone number information for each user. The User Name and Password are also entered here. Enter a new record for each HistoTrac user. Check the ‘Active?’ box to make the user name available throughout the software and to allow that user log in permission. When an employee ceases to be a user, uncheck the ‘Active?’ checkbox. The employee’s name will remain in the system but will not be available for system use.

Check the ‘Allow Edit Test History?’ checkbox if this user is to have permission to change test results after the test has completed sign out.

The ‘Member in these Organizations’ window shows the Work Areas to which this user has access. The ‘Member in these Roles’ window shows the Role and therefore security permissions this user has been provided. Selecting users when on the Work Areas and Roles screens, respectively, populates these windows.

If using Electronic Signature, direct the path to the user’s electronic signature file. Use the browse button to locate the file on your directory.

If reports are to display the name of the user logged in when printing reports, enter the appropriate display name in the ‘Name to Print in Signature Block’ field. The reports must be programmed to populate with this value.

Typically, an individual like a Key User will establish column headers, using Customize View, that are most appropriate for the laboratory. The button, ‘Copy Screen Setup’, allows this user to copy the customized column settings from another user, such as the Key User. This copying process saves individual users set up time. Each user can make selected changes to personalize without setting up column headers on all screens.
14.5.2 Security Menu

Each employee in the user table is given permission to access the menus in the software and certain functions while on that menu. The permission includes the ability to see the Tool bar items within a folder, see folders within a menu, and see menu listings (or not). These permissions are granted, and can vary, by Role. Each Role set up in the Roles menu will appear in the Security Menu.

Consider the following functions of Menu Permissions.

- If a particular function is not checked, the button (list in the window on the right) will not be available on the Tool bar for that folder.
- If all the functions for a folder are not checked, the folder (list in the center window) will not appear under the menu.
- If all the functions for all the folders within a menu are not checked, the menu (list in the window on the left) will not appear.

**Security for a Role of Administrator, showing permission for all Tool bar buttons**
14.5.3 Roles Menu

When established Roles, organize the responsibilities of the users in relationship to their use of software features.

Establishing more than one role is necessary if the Key User wishes to permit different menu access options to groups of users. An example would be providing certain menu, folder, and Tool bar permissions to Client Services and different permissions to the Lab Supervisor or Director.

Once the Role has been created, Save the record. The users in the User Table will appear in the ‘Users in the Role’ window. Place a check next to the users who will be associated with this role. When opening the individual user record, the roles to which he/she is linked will appear in the ‘Members in these Roles’ window.

Establish the desired Roles and select the users who will have the permissions associated with each Role.

Users selected for this Role

14.5.4 Work Areas Menu

When determining the work areas for a laboratory, organize the lab according to testing process done in particular sections. Example Work Areas would be Serology, Molecular, Flow, etc.

Once the Work Area has been created, Save the record. The users in the User Table will appear in the ‘Users in the Work Area’ window. Place a check next to the users who will be associated with this work area. When opening the individual user record, the work areas to which he/she is linked will appear in the ‘Members in these Organizations’ window.

The Work Areas established are available on the Test Definition screen. Each test is must be associated with a Work Area.

This connection between user, work area, and test allows the Work Management function of the software to provide work lists and screen views of testing, organized by laboratory benches. A user will see only those tests associated with the Work Areas to which he/she is linked.

For laboratories with a small staff, all users may be linked to all work areas. For larger laboratories where volume of testing requires separation of staff, the user may wish to see only those tests with which he/she is involved.
14.6 Report Dictionary

The Report Dictionary provides a listing of reports, both client-directed and internal laboratory management reports. Under the Reports menu, each report is seen on the list view. Various aspects of report availability are handled here. The Procedural and Interpretive Comments folders provide for the creation of ‘canned’ comments for selection during the reporting process.

14.6.1 Reports

The Report menu list view shows the names of the reports that are available from the various menus throughout HistoTrac. Reports specific to the functions on each menu are organized by Category. Double-click each report to view the details on the Report screen.

Reports List View showing Name, Category and Path
Consider the following functions of the Report screen.

- The Report Name is the name that appears on the Print Menu list of reports.
- The Report Type determines the menus where this report is to be printed, as seen under ‘Menu Item’. Select Patient to have the report available from the Patient Menu. Select Sample to have the report available from the Sample Menu. And so on.
- Select from the available choices under Menu Item, the folders where this report is to be listed on the Print Menu.
- Select a value in ‘Display Order’ to organize the reports under each menu according to your needs.
- Select the path to the Crystal Reports file – the file used by the software to print this report. Without proper selection of the path to the file, the report cannot be printed.
- If the user has a licensed copy of Crystal Reports on the workstation, the Crystal report file can be opened for viewing or editing from this screen. Press the ‘Edit Crystal Report’ button on the bottom of the screen.
- The remaining section of the screen provides instruction for the printing of the report. Make no changes to this information unless under the guidance of someone proficient in the use of Crystal Reports.

Report Screen for an Antibody Screening Report

14.6.2 Procedural Comments

Procedural comments that are used frequently can be placed in this table. These are comments that would apply to how the testing process was accomplished. The comments are available for selection, and for editing, from various locations in the software. They are available from every test-associated Reportable Comments and Notes fields when using the Results, Review, and Sign Off menus. (These fields must have been selected during test definition.) They are also available from the Patient Case folder.

Procedural Comments List View

<table>
<thead>
<tr>
<th>Procedural Comments</th>
<th>Procedural Code</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC</td>
<td>ABC performed by serological methods.</td>
<td></td>
</tr>
<tr>
<td>ANCA</td>
<td>ANCA positively by IIF.</td>
<td></td>
</tr>
<tr>
<td>C1Q2Q</td>
<td>C1Q2Q positively by serological methods.</td>
<td></td>
</tr>
<tr>
<td>FLOWA</td>
<td>Flow antibody screen performed by FlowFIA.</td>
<td></td>
</tr>
<tr>
<td>PRA</td>
<td>PRA performed by ELISA.</td>
<td></td>
</tr>
<tr>
<td>CH50R</td>
<td>CH50R high sensitivity test performed by sequence-based methods.</td>
<td></td>
</tr>
<tr>
<td>RIMIC</td>
<td>RIMIC obtained over NaClO4 rich gradient.</td>
<td></td>
</tr>
<tr>
<td>Seq A</td>
<td>SSF used to resolve sequence ambiguities.</td>
<td></td>
</tr>
<tr>
<td>Seq B</td>
<td>Sequence typing recommended by the manufacturer.</td>
<td></td>
</tr>
<tr>
<td>DR2/DR2R</td>
<td>Type determined by DR2/DR2R methods. Sequencing will be performed to confirm the...</td>
<td></td>
</tr>
</tbody>
</table>
Enter a Code and Description. The Code and a portion of the description are available at the time the comment is selected. The size of the comment may have some limit but multiple comments can be used to create a Reportable Comment that is unlimited.

**Procedural Comment Description**

14.6.3 Interpretive Comments

Interpretive comments that are used frequently are placed in this table. These comments would apply to the overall report of an individual's testing results. These comments can be edited at time of use to include specific patient or donor information.

**Interpretive Comments List View**

<table>
<thead>
<tr>
<th>Interpretation Code</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>BROTHER</td>
<td>The patient and his brother are HLA identical</td>
</tr>
<tr>
<td>APPEAR</td>
<td>The patient appears to be sensitized and should not receive additional transfusions</td>
</tr>
<tr>
<td>Match</td>
<td>The patient and XXXXXXXXXX appear to be a XX Antigen Match</td>
</tr>
<tr>
<td>Engraft</td>
<td>Host alleles were detected at each locus examined, at low levels close to the I...</td>
</tr>
</tbody>
</table>

**Interpretive Comments Description**

Information contained in this document is confidential to SystemLink, Inc and its principals and may not be used without permission.
14.7 Record Locks

The software is equipped with a record-locking feature that prevents more than one user from updating a record simultaneously. Each time the user opens a record, the system sends a lock message to the Record Locks list view. When the record is closed, the lock is removed, and the entry is removed from the list view. The record is now available for the second user. A message that the record is locked appears to a second user, attempting to open a record that is already open by another user.

Should the software close down without proper log off, any open record will remain locked. Upon log in, the lock will require manual removal. Go to the Record Locks menu. Highlight the locked record(s) and press the Delete button on the Tool bar.

**Example of a Locked Record**

![Example of a Locked Record](image-url)
15 Batch Test Management Module

The Batch Test Management Module provides for the management of large numbers of samples in two aspects of the testing process, 1) accessioning samples and ordering tests and 2) moving batches of tests through the work management process. Test batches can be moved to tray configurations using the Tray Management module.

15.1 Batch Accessioning

Batch accessioning facilitates the sample accessioning process, allowing large numbers of samples to be added to the Sample Log on a single screen. A listing of patients in the database is generated using a Batch Accession Rule(s) established by the user. The user selects patients from the list on whom there are new samples in the laboratory. Adjust sample dates, specimen type, etc. and accession the list of samples. If the list of patients will also have the same test(s) ordered on all, tests can be ordered here as well.

15.1.1 Establish Batch Accession Rule

To create a Batch Accession Rule, click the Sample Dictionary in Administration and choose Batch Accession Rules. Click New on the Tool bar to open a new Batch Accession Rule screen.

1. Enter a name for the Accession Rule.
2. Check the ‘Active?’ checkbox.
3. Enter a description of the purpose of the rule.
4. Press the Save button.

The rule is a query of the database, providing a list of patients who meet the criteria of the rule. For example, if the samples that arrive in the lab for antibody screening are all on renal patients, then the rule should be a query to provide a list of all renal patients. The better defined the rule, the more it will match the samples that arrive in the laboratory.

To create the query for the rule, proceed as follows:

1. Select a Field Name from the drop-down. For example, select Status.
2. Enter a condition. For this example, use ‘is (equals)’.
3. Select a Value from the drop-down. If the selection under Field Name is for a field that is table-driven, the Value field will contain the entries in that table. In this example, select Active.
4. Continue this process until the selections will provide the list of patients on whom you expect to receive samples.

Batch Accession Rule Screen in Administration

Example Queries
15.1.2 Execute a Batch Accession Rule

After creation of the Batch Accessioning Rule, the user returns to the Samples Menu, Batch Accessioning.

1. Select a Batch Accessioning Rule from the drop-down at the top of the screen.
2. Press the Execute button. A list of patients matching the Rule query will appear.
3. For each sample in the rack waiting to be accessioned, check the box to the left of the name.

**Batch Accession Rule Execution**

- **NOTE:** Use the Customize View feature to order the list as needed. For example, if the list should be in alphabetical order by Patient Name, select the Sort button under Customize View. Select Patient Name and click Ascending.

Close the screen. The list will begin with patients at the beginning of the alphabet.

Once the patients’ names have been checked, press the Order button on the Tool bar. The Batch Accession Samples screen appears. This screen provides the opportunity to identify the correct sample date, specimen type, sample count, etc. for each sample.

**List of Patients with samples to accession**
To make edits to entries on the list:

1. Highlight line(s) to be changed.
   a. Check the Select/Deselect All box to highlight the entire list.
   b. Use the Shift or Control keys plus the mouse to highlight selections from the list.
2. Select a value in the drop-down for Log Book. Press the Populate button under the drop-down.
3. The highlighted records will populate with the selection.
4. Continue this process for each of the columns.

NOTE: The user will probably select the entire list for populating the Log Book, the Specimen Type, and the Sample Count columns. Then highlight a line or groups of lines to edit the sample date and the ordering physician.

The ordering physician is filled with the physician from the patient record. Make a change if the ordering physician is different from the patient’s primary physician.

Once the columns are filled with the correct information, (if you do NOT wish to order tests here) press the Accession (and Order) button at the bottom of the screen. The Sample # column will fill with accession numbers for the new samples.

**Accessioned Samples**

If this group of patients will each have the same test ordered, press the Select Tests to Order button PRIOR to pressing the Accession (and Order) button. The next screen offers Tests to Order. Select tests from the Individual Tests or from the Batteries list by double clicking the desired test(s). After selecting tests, then press the Accession (and Order) button. The samples will be accessioned and the tests ordered in one step.

**Test Ordering during Batch Sample Accessioning**
Close the Batch Accessioning screen. The samples will be found on the appropriate logbook. If tests were ordered, they will be in the Work Management process according to the default assignment instruction of the ordered test(s).

15.2 Batch Ordering

Once samples are accessioned, a separate query can be set up to order tests on groups of samples. A Batch Order Rule is used to generate a list of patients who will be tested in the same manner. For example, all patients who are tested by ELISA would be grouped for test ordering and all patients who are tested by Flow would be grouped.

The Batch Order Rule can be created to filter patients based on such attributes as sample dates, sample number, patient category and status, PRA values, etc. The user will work with the query choices to establish a rule(s) that meet the needs of the various testing algorithms in use.

15.2.1 Establish a Batch Order Rule

To create a Batch Order Rule, click the Sample Dictionary in Administration and choose Batch Ordering Rules. Click New on the Tool bar to open a new Batch Order Rule screen.

1. Enter a name for the Order Rule.
2. Check the ‘Active?’ checkbox.
3. Enter a description of the purpose of the rule.
4. Press the Save button.

The rule is a query of the database, providing a list of patients who meet the criteria of the rule. For example, if antibody screening for all renal patients is done by flow cytometry methods, then the rule should be a query to provide a list of all renal patients. If some renal patients are tested by flow and some by ELISA, then two rules would be created to generate two lists of patients, one for ordering flow tests and another for ordering ELISA tests. There are a number of fields from which to choose to define the rule (query).

To create the query for the rule, proceed as follows:

1. Select a Field Name from the drop-down. For example, select Category.
2. Enter a condition. For this example, use ‘is (equals)’. See the screen view below for a list of the conditions available for selection.
3. Make an entry in the Value column.
   a. If the selection under Field Name is for a field that is table-driven, the Value field will contain the entries in that table. In this example, select Renal.
   b. The selection can be more than one entry from the table. If you would like to select more than one category, use the Condition ‘IN’. Enter the Value with the following format. (‘Renal’, ‘Liver’), where Renal and Liver are entries in the Category table.
4. Continue this process until the selections will provide the list of patients on whom you expect to receive samples.

Create a Batch Order Rule
In the above screen view, all renal patients whose Current PRA value is greater than (select > from the drop-down) 10% will appear when the rule is executed.

Additional examples:

**Using Prompt User, the sample date is entered when the rule is executed, allowing the user to enter a different date each time the query is used.**

To order an antibody identification test, use a Specificity search, not equal to ‘empty’ to yield a list of patient who have antibody specificity.

15.2.2 Execute a Batch Order Rule

After creation of the Batch Ordering Rule, the user returns to the Samples Menu, Batch Ordering.

1. Select a Batch Ordering Rule from the drop-down at the top of the screen.
2. Press the Execute button. A list of patients matching the Rule query will appear.
3. For each patient on whom a test is to be ordered, check the box to the left of the name.

NOTE: Use the Customize View feature to show on the list view the information needed to make ordering decisions. Include such fields as PRA history using Current and Peak Class I/II PRA values and dates.

This Specificity rule shown above provides patients whose Class I Antibody field is not empty. Also showing on the list view is the patient’s peak and current PRA values. These additional pieces of information may assist the user in making the test ordering decision.

**List of Patients after Executing the ‘Specificity’ Batch Order Rule**
15.2.3 Order Tests

After executing the rule, place a check in the box to the left of each name on whom a test is to be ordered. If all entries on the list are to have the test ordered, use the ‘Select All’ check box to the left of the Execute button.

Then press the Order button on the Tool bar. The Order Tests screen appears. Make a selection from the Individual Tests or Batteries lists.

Order Tests screen

Keep in mind that each patient selected will have the same test(s) ordered. The tests are ordered on existing samples. The most current sample date that has been accessioned will appear on the list. If there are multiple samples within a user-entered data range, only the most current sample will be listed.

15.3 Test Batches

Test batches are groups of ordered tests, usually of the same test. Tests can be assigned to a batch for efficient movement through the Work Management process. Batches are created under the Work Management Menu. Tests are assigned to the batch and move to the Results, Review, and Sign Out menus grouped as a batch.

The batching of tests is particularly useful for loading tray maps with the Tray Wizard of the Tray Management module. Tray maps can then be exported through an interface to third party software. Results are returned by import of a file of batch results.
15.3.1 Create a Test Batch

From the Work Management Menu, select Test Batches. Previously created batches are seen on the list view.

**Test Batches List View**

To create a new batch:

1. Press the New icon on the Tool bar.
2. Complete the Batch Name, Review Cycle, and Maximum Tests.
3. Check the 'Active?' check box.
4. Save the batch and Close the screen.

**New Batch Screen**

NOTE: The maximum size of the batch will limit the number of tests the system will place in the batch. Using zero as a batch size will allow for the assignment of an unlimited number of tests.

Once tests are assigned to the batch, they will be listed in the Tests window.

15.3.2 Assign Tests to a Batch

Tests can be assigned to a batch from the Work Management/Test Assignment menu or by default on the test setup screen in Administration.

15.3.2.1 To place unassigned tests into a batch from the Work Management menu:

1. Click Test Assignment to view a list of unassigned tests.
2. Use the Test Types filter drop-down at the top of the screen to list each test type separately.
3. Highlight the desired tests.
4. Right click the mouse and select Assign from the menu list.

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5. Select Batch from the second menu list.
6. Select the batch name from the third menu list.

Test Assignment from the Work Management Menu

15.3.2.2 To place tests into a batch by default through test setup:

1. From Administration menu, Test Dictionary, Test Definitions, select the test on which you wish to set up default assignment.
2. Under the Default Assignment frame, click the radio button to the left of Batch. The Assign To drop-down will contain the list of active batches. Select the desired batch.

Test Assignment by Default from the Test Definition Screen

15.3.3 View tests assigned to a batch

Once tests have been assigned to a batch, the tests can be viewed from the Test Batches screen. As tests are completed, reviewed and signed out, the status of the test is seen from the list view.
15.3.4 Enter Results for Tests in a Batch

Once testing is complete, the user returns to the software to enter test results.

To enter results:

1. Go to the Results menu and select By Batches.
2. Use the Test Batch drop-down at the top of the screen to select a single batch. (If all tests in the batch have a status of 'Assigned', the list of tests seen here should be the same as the list on the Test Batch screen.)

3. To enter results, highlight selected tests or the entire batch. Right-click the mouse and select Complete.
### Tests Selected for Completion by Batch

<table>
<thead>
<tr>
<th>Result Batch</th>
<th>Test Batch</th>
<th>ELISA Match</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name</td>
<td>MR Location</td>
<td>Test</td>
</tr>
<tr>
<td>Tom Jones</td>
<td>123456</td>
<td>ELISA</td>
</tr>
<tr>
<td>Jane Doe</td>
<td>654321</td>
<td>ELISA</td>
</tr>
<tr>
<td>Bob Smith</td>
<td>789012</td>
<td>ELISA</td>
</tr>
</tbody>
</table>

**Add To My Work List**
- Patient Name: John Smith
- MR Location: 34567
- Test: ELISA
- Test Date: 04/04/2023
- Result: Routine
- Priority: Low

### List of Tests Ready for Results Entry

<table>
<thead>
<tr>
<th>Test Result ELISA Tests</th>
<th>Edit Help</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPECIMEN</td>
<td>Call</td>
</tr>
<tr>
<td>Name: John Smith</td>
<td>123456</td>
</tr>
<tr>
<td>Name: Jane Doe</td>
<td>654321</td>
</tr>
<tr>
<td>Name: Bob Smith</td>
<td>789012</td>
</tr>
</tbody>
</table>

### Completed Test Results

5. Complete the results. Check the Save Data and Result Complete checkboxes for each completed test.
15.3.5 Review and Sign Out Tests by Batch

The batch or group of tests move from the Results menu to Review and/or Sign Out, depending on the instruction of the test in the batch or the instruction for the batch.

NOTE: If the review cycle for the test is different from the review cycle of the batch, the review cycle for the batch will be used.

From the Review Menu, select By Batch. Select the Batch from the drop-down at the top of the screen. The list of tests ready for review will appear on the list view.

Review by Batch - List View

To Review the batch of tests, highlight the list of tests. Right-click the mouse and select Review from the menu.

Selected Tests for Review by Batch

Review the results that were entered previously. Corrections can be made to the existing data. Comments can be added to either Notes or Reportable Comments. Results can be returned to the ‘bench’ for repeat.

Completed Test Review

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The process of sign out for a batch follows the same steps as for review. From the Sign Out Menu, select By Batch. Select the batch from the drop-down. Highlight the tests to be signed out.

**Completed Test Sign out**

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
<th>Test Method</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>100</td>
<td>ELISA</td>
<td>Antibody Scn performed by LAT</td>
</tr>
</tbody>
</table>

NOTE: Samples can be placed into inventory from Results, Review, and from the Sign Out screens for batches of tests.

15.3.6 Test Batch Management

Test batches are created, used, and closed as tests move through the order, assignment, completion, and sign out process.

If test batches are created for each reagent batch (for example, one batch per ELISA plate), all tests in a batch will probably be moved through the system together. The batch will be made inactive when the plate of tests has been signed out.

If test batches are created for a time period (each month), the batch may contain a combination of tests statuses - assigned tests through signed out tests. In this example, batches would remain open for the testing period, not just for the completion of a single plate.

At any time, the user can open the Test Batches screen and review the test status of each of the tests in the batch. Select the column headers on the batch screen to provide the best information for reviewing batch content.

15.3.6.1 Closed Batches

When a batch is to have no more tests assigned to it, check the “Closed?” checkbox on the Test Batch screen. This should be done when the testing process is to be started. If new tests are arriving in the laboratory, they can be assigned to new/different batches. The closed batch will not accept additional tests.

15.3.6.2 Active batches

Batches with the ‘Active’ checkbox checked will appear in any batch drop-down through out the software. Once all the tests in a batch have been signed out and no additional tests are to be added to the batch, the batch can be made inactive. Open the Test Batch screen and uncheck the ‘Active’ box.

**Test Batch – Not Active and Closed**
16 Tray Management

The Tray Management Module is used to place samples, reagents, and controls into locations on trays – either to print a tray map or to export a tray definition file. This module uses a query mechanism to select groups of patients from the database, or reagents from the reagent table, to place them in specific locations on a tray (plate). If using the Batch Test Management module, a tray-building wizard creates tray(s), using tray templates, and placing the samples from a batch of tests into tray locations.

The user can create tray templates that are used again and again, either when using the tray wizard or when selecting samples from the database. The user determines the order of placement of samples/reagents, creates the tray names, and determines the content.

The module supplies a reagent table for addition of antisera, primers, probes, or controls. These reagents can also be placed into an inventory system.

The tray definition files containing samples on which tests have been ordered are most often used to send information to another system's software. For example, HistoTrac can export a tray definition file to ELISA antibody screening software or to Luminex technology software.

NOTE: The import/export process is accomplished by an interface with the reagent software. The import of this file saves the user data entry in that system prior to running an assay. Results from the third party system are returned to HistoTrac. This interface is created specifically for the third party software and is a separate module from Tray Management.

16.1 The Tray Dictionary

In Administration, the Tray Dictionary is the location for setting up new trays, viewing the content of existing trays, and creating reagent records.

A summary of the Tray Dictionary menus:
- Trays – create tray definitions
- Tray Type Codes – list types of trays used in tray definition
- Tray Group Codes – group trays, usually by Blood Group for screening purposes
- Antibody Reagent – list antibody records
- Dilution Codes – list dilution values
- Antiserum Reagent - list antisera records
- Primer Reagent - list primer records
- Probe Reagent - list probe records
- Control Reagent - list control records
- Tray Characteristics
- Well Characteristics

This manual will describe the creation of trays with controls and samples. Reagents will be covered for specific users.

16.1.1 Create a Tray

Most trays used in the laboratory have a standard format. The controls are in specified locations, the tray is plated/read in a certain well order, and the contents are singular or duplicate. Creating a template that can be used over and over is the most efficient method for creating trays with different sample content.

16.1.1.1 Create a Tray Template

In Administration, select Trays. Existing trays are seen on the list view at the right.
Trays – List View

To create a template:


New Tray Screen

2. Complete the tray name and tray size.
3. The screen opens with the tray configuration designed for portrait tray layout. (Columns A-F and rows 1-12). If the tray is to be configured in landscape layout (Columns 1-12 and rows A-H), check the ‘Left to Right View?’ box. The coordinates of the layout will change. The number of columns and rows is determined when selecting the tray size.
4. Select the Tray Type of Template. This drop-down contains entries from the Tray Type table which is user defined. In addition to user entries, an entry of Template is provided in the software. The template is to be used for creating other trays, either using the Copy command or when using the Tray Wizard.
5. Complete Lot Number and Expiration Date, if desired.
6. Save the tray.
7. To establish the order in which samples/reagents will be placed on the tray, take the following steps.
   a. Press the ‘Set Tray Wizard Population Order’ button.
b. With the cursor in the top left well, right click the mouse. A menu list appears. (This assumes the first well to load is the top left well.)

Tray Definition - Begin Population Order

![Tray Definition - Begin Population Order](image)

- Select Start Recording from the menu.
- With the mouse, click in each well in the order the tray is to be loaded. A small number appears in each well. Continue until the well order is defined.

Record Population Order

![Record Population Order](image)

e. If an error is made, use the right-click menu to select Clear Well or Clear Order.
f. If using standard serpentine or standard 2-column patterns, select the choice from the right-click menu.

8. Most trays contain control samples in designated locations. Adding controls to the template will facilitate completing the tray more quickly. If using the template in the Tray Wizard, the wizard assumes controls have already been added. The wizard populates all empty wells.
   a. Press the Show Well Contents button to hide the population order.
   b. Use the Reagents search screen on the right to list the controls found in the control table. Check the ‘View Full Search Screen’ check box to change the view as seen below.
Search Screen in Partial and Full View

c. Use the search features to list the controls in the lower right window.
d. Position the cursor in the location where the control is to be placed. Double-click the control name. It will populate the highlighted location. The cursor will move to the next well in the population order. Continue to select controls, placing them as you wish by moving the mouse to the desired wells.

Template Control Placement

9. Save the tray definition.
10. Print a Tray Layout by pressing the Print button.

16.1.1.2 Load a Tray from the Tray Dictionary

With the population order and the control content defined in a template, loading a tray involves placing samples or reagents into the remaining wells of the tray. This can be accomplished from the Tray Dictionary (usually for loading reagents or samples, not in the context of an ordered test) or from the Work Management Menu/Test Batches menu (usually for samples on which a test is to be completed). The Tray Wizard will be described in the next section.

Load a tray as follows:

1. Select a template from the Trays list view.
2. Press the Copy button on the Tool bar.
3. The Copy Tray screen appears. Enter the name of the new tray. It will have the same characteristics as established in the template.
Copy Tray Screen to Rename a Template

4. Open the tray from the list view by pressing the Open button on the tool bar or double-clicking the tray name. (Avoid the use of the right-click menu here, as that will disable the right-click menu once the tray definition screen is open.)

5. On the newly copied tray, change the Tray Type from Template to the appropriate choice.

New Tray with Tray Type modified

6. Expand the Search Screen View.
7. Select search criteria from the Field Name. Enter a condition. Select a Value. The example below selects group A patients from the database.

NOTE: Use Customize View to order the fields in the search window to provide the most useful information.
8. Place the cursor in the first well to receive a sample. Double click the sample in the search window. The tray will populate according to the population order set for the template.

**Loading Samples into Well Locations**

9. If the same sample is to be duplicated, use the right-click menu. Select ‘Duplicate Sample in Next Well’.
10. Continue until the tray is completed.
11. Return the screen to full view of the tray to double-check well contents.
12. Save the completed tray.
NOTE: If the tray is to be used in a third party system, the user will be provided with a utility application (HistoTray) to accomplish the export. HistoTray is associated with a reagent or instrument interface.

16.2 The Tray Wizard

The Tray Wizard button is found on the Test Batches screen. The wizard is used to place a batch of samples (on which ordered tests are to be completed) into well locations quickly. The tests have been placed in the batch for the purpose of grouping them for the testing process.

In preparation for using the wizard, create a batch and assign tests to the batch as described in the Batch Test Management section. Proceed as follows:

1. From the Work Management Menu, select Test Batches. Open the batch containing tests for which the samples are to be placed in well locations on a tray.

**Test Batch Ready to Build a Tray**

2. Press the ‘Build a Tray from the Batch’ button.
3. The Build a Tray screen appears.
4. Select a Tray Template from the drop-down. All active templates that have been defined in the Tray Dictionary are available for selection.

**Select a Template**

5. Complete the remaining instructions on the Build a Tray screen.
   a. Complete Tray Information
      i. Check 'Create only one tray'. Use when the batch size is equal to or small than the empty wells on the tray template.
      ii. Check 'Create as many trays as needed'. Use when the batch size exceeds the number of empty wells on the tray template. The system will auto-number multiple trays.
   b. Enter a Tray Name. If creating multiple trays, the system will add a '-1', '-2' after the name of the tray.
   c. Select a Tray Type.

**'Build a Tray' Information**

6. Press the Build button. View the loaded tray.

7. Additional samples can be added using the search tool on the right.
The new tray can also be viewed from the Trays menu under Tray Dictionary. It will be available for selection when using the HistoTray utility.
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