OpenELIS Newborn Screening Follow-up Web Portal User Guide



Table of Contents

General Features	3
Logging in	3
Account Menu	
Module Buttons and Menus	3
Alerts	
News	4
Help Text	4
Changing Your Password	
Questions/Help	4
Newborn Follow-Up Module	5
All Active Cases	5
Sorting, Filtering, and Searching	5
Case Table	
Adding a Tag	
Tag Legend	
Taking a Case	
Refresh Cases	
Newborn Contacts	
My Active Cases	
Case Details	10
Patient Tab	10
Patient Information	10
Lab Screening Results	13
Case History Tab	16
Condition-Specific Tabs	18
Lab Screening Results	18
Condition History	19
Adding an Event	19
Case Note	19
Recommendation	23
Recommendation Letter	25

Attachment	26
Confirmatory Test	27
Family Contact Call	29
Genetic Counseling	34
Condition Short-Term Outcome	38
Condition Long-Term Outcome	40
Case Outcome	41
Ready To Close Cases	42
Closed Cases	43
Query Fields	43
Patient Information Table	45
Reopen a Case	46
Patient Lookup	47
Query Fields	47
Patient Information Table	48
Newborn Contacts Module	50
Querying for Existing Contacts	50
Adding or Updating a Contact	52
Monitor Patients	53
General Reports	57
Final Report Statewide Screen	57
Query Fields	57
Viewing Final Reports	59
Spreadsheet View Statewide Screen	60
Test Status Statewide Screen	62
Newborn Reports	64
Newborn CollN Report	64
Newborn Birth Match Report	66
Newborn Feeding Report	69
Newborn Samples QA Statewide Report	71
Newborn State Summary Report	73
Newborn Turnaround Statewide Report	77

The OpenELIS Web Portal has been redesigned to be more responsive; it can now be used easier on tablets, laptops, and cell phones.

General Features

The general features of the OpenELIS Web Portal are described in this section.

Logging in

- Go to the State Hygienic Laboratory at The University of Iowa's web site at www.shl.uiowa.edu .
- Click on the green Test Results button on the left-hand side.
- Click on the green **OpenELIS** button.
- Login using your username and password. (This is a secure site. Your username and password are encrypted as they are sent for authorization.)
- If using a shared computer, please click **Logout** on the **Account** menu and then close the browser after completing the session.
- Supported desktop web browsers are recent versions of: Firefox, Chrome, Opera, Safari, and Microsoft Edge (version 15 and above). Mobile browser compatibility includes Apple iPhone and iPad and Android devices.

Account Menu

- The Account menu in the top right corner of the Home page displays the name and username of the user.
- There are links to logout of the web portal and to change the user's password.
- The user can adjust the font size of the screen text and change the Display Mode (Dark, Calm, Lite).
- There are also links to related forms and user guides.



Figure 1 Account Menu

Module Buttons and Menus

• The **Home** page of the OpenELIS Web Portal contains a button for each module for which permissions have been assigned. The menus at the top also lists these modules. Open a module by clicking on its button or selecting it from the menu.



Figure 2 Newborn Screening Follow-Up Module Buttons

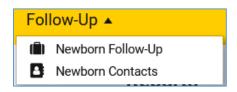


Figure 3 Follow-Up Menu

Alerts

• A red circle above the bell icon denotes that there are one or more active alerts pertaining to the laboratory and the web portal. Click on this icon to display the alerts. Active alerts will also display at each login.

News

• A red circle above the newspaper icon denotes that there are one or more new news articles pertaining to the laboratory and the web portal that have been posted since the last time that the user logged in. Click on this icon to display the news articles.

Help Text

• A **Help** button located in the lower right corner of each screen will display helpful information regarding the use of that screen.

Changing Your Password

- Click Change Password on the Account menu and follow the designated steps.
- Keep your new password secure. If you must write it down, be sure to keep it in a safe place.
- Passwords must meet the following requirements:
 - Password is case sensitive.
 - Must be at least 15 characters long.
 - Must be no more than 25 characters long.
 - Must not include any of the following values: test password
 - Must not include part of your name or username.
 - Must not include a common word or commonly used sequence of characters.
 - Must have at least three types of the following characters:

Uppercase letter (A-Z) Number (0-9)
Lowercase letter (a-z) Symbol (!, #, \$, etc.)

Questions/Help

• Questions regarding the OpenELIS Newborn Screening Follow-up Web Portal may be directed to shl-openelis-support@uiowa.edu or to 319/335-4451.

Newborn Follow-Up Module

The Newborn Follow-Up module is used by Newborn Screening follow-up staff, state coordinators, genetic counselors, and medical consultants to manage and complete their cases and documentation.

Click on the <u>Newborn Follow-Up button</u> or the link in the <u>Follow-Up menu</u> to open this module. The major divisions of this module are separated into tabs that are located at the top of the screen.

All Active Cases

This tab will be displayed by default when the module is opened. All active cases will be displayed regardless of owner.

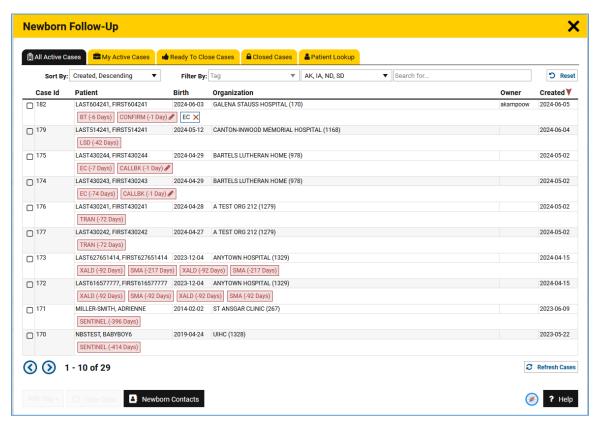


Figure 4 All Active Cases Tab

Sorting, Filtering, and Searching

Cases on this tab can be sorted, filtered, or searched. These tools are described below.



Figure 5 Sort By, Filter By, and Search for Tools

Sort By

The cases on this tab can be sorted by case id, patient's last name, birthdate, "Report To" organization (submitter), case owner, or case created date. The sort order can be either ascending or descending. The default sorting is by Created date and in Descending order. Click on a Column name and/or Order to change the sorting. The Reset button will revert the tab back to the default sorting.



Figure 6 "Sort By" Dropdown Menu

Filter By

The cases on this tab can be filtered by assigned tag (i.e., BT Result, Call Back, Early Collection, Transfused, etc.) This can aid in restricting the cases that are displayed to specific situations. Click on a tag name to filter by that tag.



Figure 7 "Filter By:" Tag

The cases can also be filtered by state (if the user has permissions to multiple states). Click on a state to filter by that state. The default view is to display cases from all of the states to which the user has permissions.

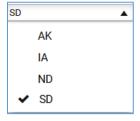


Figure 8 "Filter By:" State

The Seset button will revert the tab back to no filtering.

Search for...

This field can be used to search for any cases on this tab that match the text that is being entered. Examples include searching by a partial or full patient name or organization name, case id, organization id, birth date or created date. Tags and owners cannot be searched in this manner, but cases can be filtered by tags and sorted by owners.



Figure 9 "Search for..." a patient's name

2023-04-12

Figure 10 "Search for..." a patient's birth date or a case created date

The D Reset button will revert the tab back to its initial view.

Case Table

All active cases are displayed in a table. The Solutions are used to page through the cases. The columns of the table are described below.

Case Id

The id of the case is displayed here. Every case that is created is automatically assigned an id by the system for referral. The case id can be emailed by itself non-securely as it does not disclose any protected health information.

Patient

The last name, first name of the newborn is displayed in this column.

Birth

The birth date of the newborn is displayed here.

Organization

The name and OpenELIS id of the "Report To" organization that is linked to the initial newborn screening sample is displayed here. Results are reported to the "Report To" organization through mail, the OpenELIS Web Portal, and/or an electronic results interface.

Owner

The username of the owner of the case (if it has been claimed) is displayed in this field.

Created

The date that the case was created is displayed in this field.

Tags

Any tags that are present on a case are displayed below the first row of that case. Active tags remind the user as to when a specific action needs to be undertaken. Click on a tag to view its details.

Adding a Tag

Tags are either added automatically by the case scanning software that runs continually in the background or manually by a user. Add a tag manually by checking the box in front of the patient's name, clicking the **Add Tag** button at the bottom of the screen, and selecting the tag to be added.

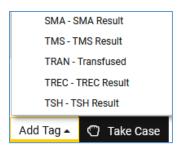


Figure 11 Manually Adding a Tag

The tag window will pop up. Its fields are described below. with the User and Created date and time fields already populated.

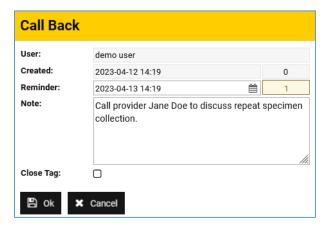


Figure 12 Tag Pop-up Window

User

This field will be populated with the name of the user who created the tag. A tag that is automatically created by the case scanning software will have "system user" for the user.

Created

This field will be populated with the date and time that the tag was created. The field to the right of the Created field displays the number of days since the tag was created ("0" for a tag created today).

Reminder

The date and time to display the tag can be set in this field. The field to the right of the Reminder field displays the number of days until the tag will be displayed. A positive value is in the future; a negative value is in the past The "reminder number of days" value is displayed in parentheses to the right of the tag name for open tags.



Figure 13 Past Due Tag

Note

A note can be added to a tag by entering it into this field.

Close Tag

A tag can be closed manually by a user by checking this box. The date and time that the tag was closed is displayed to the right of this checkbox.

Draft Version 2 2024 Michael B. Hayek 8

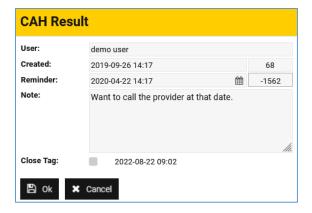


Figure 14 Pop-up Window of a Closed Tag

Tag Legend

Tags are color-coded to alert the user as to the timeframe of when they are due. They may also have one or more icons that signal other characteristics of the tag. Click on the icon at the bottom to view the tag legend.

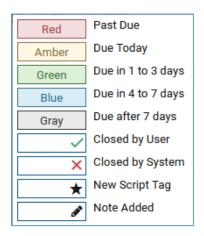


Figure 15 Tag Legend

Taking a Case

Take ownership of a case by checking the box in front of it and clicking the button. Your username will be displayed in the **Owner** column. The case will now be additionally displayed on the My Active Cases tab.

Refresh Cases

The cases that are displayed on this tab can be updated in real time by clicking the Refresh Cases button

Newborn Contacts

Click on the button to pop up this module. The <u>Newborn Contacts</u> module is described in a later section.

My Active Cases

The user's active cases will be displayed on this tab.

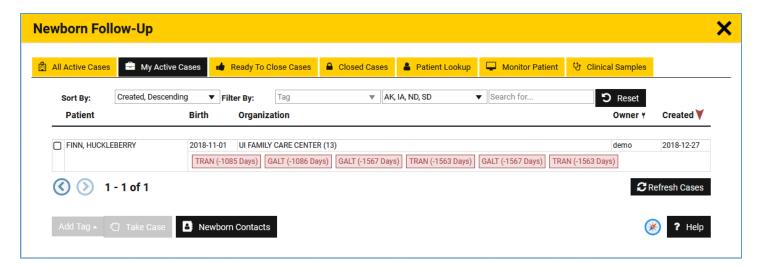


Figure 16 My Active Cases Tab

The features of this tab work in the same manner as the All Active Cases tab.

Case Details

Click on the patient's name in the All Active Cases or My Active Cases tab to view the case details.

□ NBSTEST, BABYBOY5

Figure 17 Patient's Name

The Case Details screen for that patient will be displayed. Click the button to go back to the All Active Cases or My Active Cases tab.

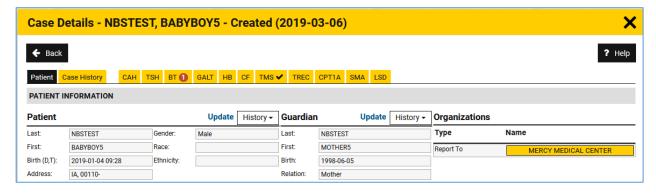


Figure 18 Case Details Screen

The Case Details screen is divided into a number of tabs: Patent, Case History, and one for each screening condition.

Patient Tab

There are two sections of the Patient tab: Patient Information and Lab Screening Results.

Patient Information

The patient's and guardian's demographic information (both current and historical) can be displayed and updated here. Organization information is also displayed here. The fields in this section are described below.

Patient Last

The last name of the patient is displayed in this field.

Patient First

The first name of the patient is displayed in this field.

Patient Birth (D,T)

The birth date and time of the patient is shown here.

Patient Address

The residing address of the patient is displayed here, if provided.

Patient Gender

The assigned sex at birth of the patient is shown here. Options are Female, Male, and Unknown.

Patient Race

The race of the patient is displayed in this field, if provided.

Patient Ethnicity

The ethnicity of the patient is shown here, if provided.

Guardian Last

The last name of the patient's guardian is displayed in this field, if provided.

Guardian First

The first name of the patient's guardian is shown here, if provided.

Guardian Birth

The birth date of the patient's guardian is shown here, if provided.

Guardian Relation

The relationship of the guardian to the patient is displayed here, if provided.

Organizations

The type and name of each organization that is linked to the newborn screening sample(s) is displayed here. Types of organizations include "Report To" (results are reported to this organization through mail, the OpenELIS Web Portal, and/or an electronic results interface), "Secondary Report To" (results are mailed to this organization), and "Birth Hospital" (the patient was born at this organization).

Click on the yellow name of the organization to pop up its **Organization Contact** window to view its details.

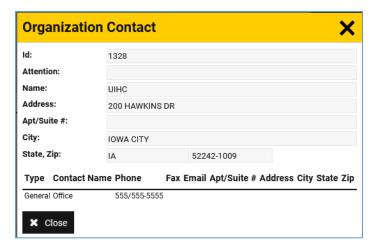


Figure 19 Organization Contact Pop-up Window

Patient and Guardian History

The history of the patient's and guardian's demographic information can be viewed by clicking on the History dropdown button at the top of the corresponding section. There are four history records that can be viewed: Patient, Patient Address, Guardian, and Guardian Address.



Figure 20 History Dropdown Button

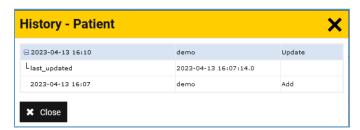


Figure 21 History - Patient Pop-up Window

It is usually easiest to read the history from the bottom up and to expand the 🗎 nodes by clicking on them.

Click the appropriate **Update** button to update the patient's or guardian's demographic information. Enter the updated information into the pop-up window and click the **OK** button.

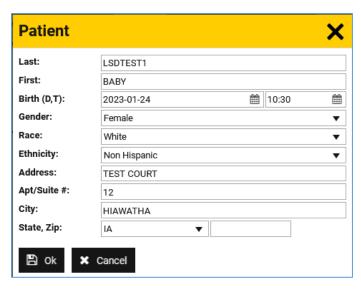


Figure 22 Patient Update Pop-up Window

Lab Screening Results

Newborn screening results from one or more samples are displayed in this section along with any attachments to each sample. The fields in this section are described below.

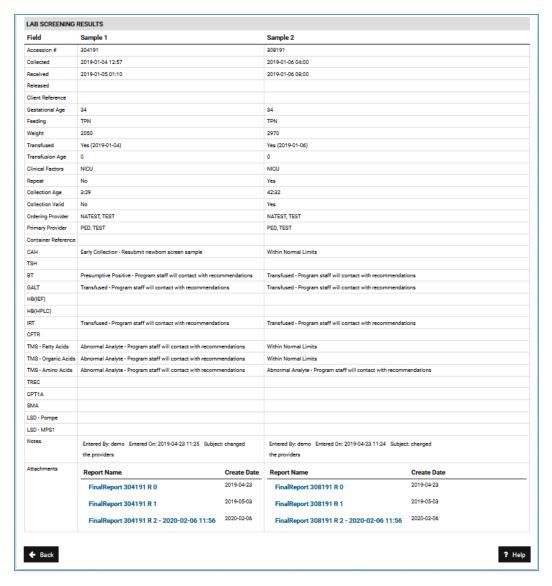


Figure 23 Lab Screening Results

Accession

The number (id) assigned to the sample by the performing laboratory.

Collected

The date and time that the sample was collected is displayed in the format of YYYY-MM-DD HH:MM.

Received

The date and time that the sample was received at the performing laboratory is displayed in the format of YYYY-MM-DD HH:MM.

Released

The date and time that the results of the entire sample were released is displayed in the format of YYYY-MM-DD HH:MM. This corresponds to the date and time that the last test on the sample was released.

Client Reference

An identifier that was provided for the sample or patient by the submitting organization. It could be the organization's sample number, a patient ID, Chart ID, or Medical Record Number (MRN).

Gestational Age

This is the common term used during pregnancy to describe how far along the pregnancy was at birth. It is measured in weeks, from the first day of the woman's last menstrual cycle to the newborn's birth date.

Feeding

The feeding method of the newborn is displayed here, if provided. Options include Breast Milk, Formula, TPN, and their various combinations, and None of the above.

Weight

The current weight of the newborn in grams when the samples was collected is shown here, if provided.

Transfused

The transfusion status of the newborn for any blood products before sample collection is displayed here. Values include Yes, No, and Unknown. The date of the last transfusion (if provided) is displayed to the right in parentheses in the format of YYYY-MM-DD.

Transfusion Age

This value represents the age of the transfused blood products in the newborn in days. It is calculated by subtracting the date of the last transfusion (if provided) from the sample collected date.

Clinical Factors

Factors that can affect screening interpretations and short-term follow-up recommendations are displayed here, if provided. Options include whether the newborn is in the NICU, has Meconium Ileus, or both.

Repeat

This field denotes whether the sample is for a repeat screen. Values are Yes and No.

Collection Age

The age of the newborn at the time of sample collection in the format of HH:MM. It is calculated by subtracting the newborn's birth date and time (if provided) from the sample collected date and time (if provided).

This field will be empty if the software cannot calculate or estimate it. This is caused by the Collected Date, Collected Time, Birth Date, and/or Birth Time being unknown. If the Collected Date is 2 days after the Birth Date and either or both the Collected Time and Birth Time are unknown, the Collection Age will be estimated to be 48:0 hours and the Collection Valid field will be "Yes". An estimation is also calculated when the Collected Date is greater than 2 days after the Birth Date for samples where either or both the Collected Time and Birth Time are unknown.

Collection Valid

This field denotes whether the sample collection was valid. Collections are valid when the <u>Collection Age</u> of the newborn is \geq 24:00 hours. Values include Yes, No, and Unknown. An "Unknown" value is displayed when the <u>Collection Age</u> cannot be calculated or estimated by the software and, thus, is empty.

Ordering Provider

This field displays the last name, first name of the ordering health care provider of the newborn screen.

Primary Provider

This field displays the last name, first name of the primary care provider of the newborn, if provided.

Container Reference

This field can be used to display the serial number of a newborn screening dried blood spot collection card.

Test Interpretations

The interpretation for each newborn screening test that has been released is displayed in these fields.

Notes

Both external (notes that are displayed on the Final Report), and internal sample notes are displayed in this field. An external sample note will be displayed first, followed by any internal sample notes. Only the text of an external sample note is displayed. The complete details of an internal sample note will be displayed: Entered By, Entered On, Subject, and the text of the note.



Figure 24 External and Internal Sample Notes

Attachments

Any attachments to the sample are displayed in this field. Attachments can include various versions of the results report (begins with the words "FinalReport"), the test request form (begins with the letters "TRF"), email correspondence, and instrument output. The date that the attachment was created in OpenLIS is also displayed. Click on the blue filename to pop up the attachment.



Figure 25 Sample Attachments

Case History Tab

The Case History tab is used to document all of the case management work that have been performed on behalf of the newborn. This includes documenting case notes and confirmatory testing, making medical recommendations, and assigning outcomes. The various tools on this screen are described below.

Case Event Dropdown Menu

The dropdown menu in the upper left corner of this tab contains all of the events that can be added to a case.

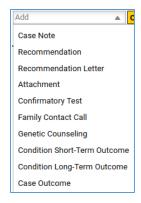


Figure 26 Case Event Dropdown Menu

Select the event from the list that is to be added to the case. Each type of event will be described in detail in a later section.

Close Case

Click the Close case button to close the case when the casework is finished.

Sort By

The events that are listed can be sorted by either the "Entered On" column or the "Event Type" column. The sort order can be either "Ascending" or "Descending". The default sorting method is to display the events by the "Entered On" date in "Ascending" order. This can be changed by selecting from the "Sort By" dropdown menu.

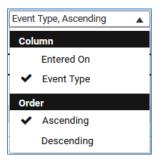


Figure 27 "Sort By" Dropdown Menu

Events

The total number of events that are displayed on this tab is shown here.



Figure 28 Number of Events

Sorted By

The current sorting method that is being used on this tab is shown here.



Figure 29 Current Sorting Method

Events Displayed

All of the events that have been added to the case are displayed on the remainder of the tab. They are numbered for easy referral. Each event type will be described in detail in later sections. Click on **Update** in the upper right corner of an event to update its information at any time before a case is closed. Exception: Notes that have "Entered By", "Entered On" and "Subject" information cannot be edited at a later time. However, a new note can be added to further explain or clarify a previous note.

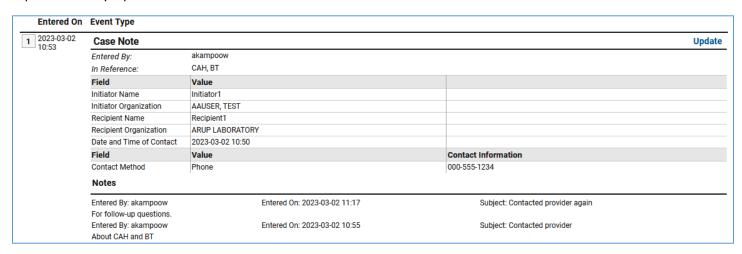


Figure 30 An Event Displayed

Condition-Specific Tabs

The remainder of the tabs on the Case Details screen are specific to the conditions that are being tested. If a red circle to the right of the tab's name is present, it will contain the number of abnormal results that exist for that condition on the newborn. For example, a "2" denotes that there are 2 abnormal results for that condition. They could be on the same newborn screening sample or different samples. A vote to the right of the tab's name denotes that the condition has been closed by a user. If there is neither a red circle nor a checkmark to the right of the tab's name, the condition can be presumed to have normal results. Early Collection, Early Collection Unknown, Transfused, Transfused Unknown, and Poor Quality are not considered abnormal results and, thus, will not trigger a red circle's number to increment.

There are two sections of a condition-specific tab: Lab Screening Results and Condition History.

Lab Screening Results

This section displays the accession numbers, collection dates, test results, test interpretations, and any test notes for the specific condition. Each sample is numbered for user convenience.

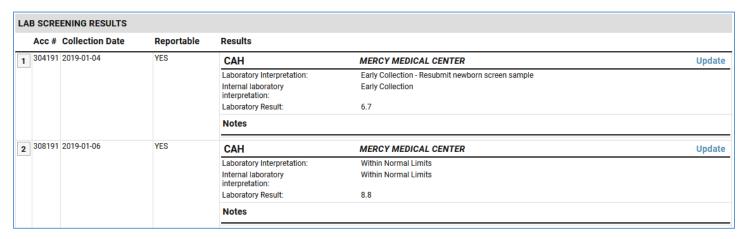


Figure 31 Lab Screening Results

Condition History

This section displays any events that have been added to the case that are specific to that condition. The events are numbered for user convenience and the <u>sorting method can be changed</u>. The <u>total number of events</u> that have been added and the <u>current sorting method</u> are also displayed. Click on **Update** in the upper right corner of an event to update its information at any time before a case is closed. Exception: Notes that have "Entered By", "Entered On" and "Subject" information cannot be edited at a later time. However, a new note can be added to further explain or clarify a previous note.

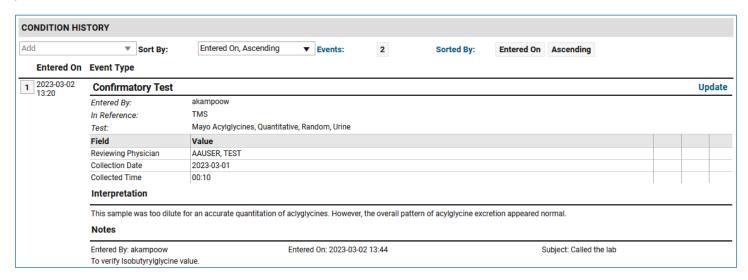


Figure 32 Condition History

Adding an Event

Click on the <u>Case Event Dropdown Menu</u> from either the <u>Case History tab</u> or a <u>condition-specific tab</u> to add an event to the case. The event types are described below.

Case Note

A case note can be used to document any type of correspondence/contact regarding the case. The fields on this pop-up screen are described below.

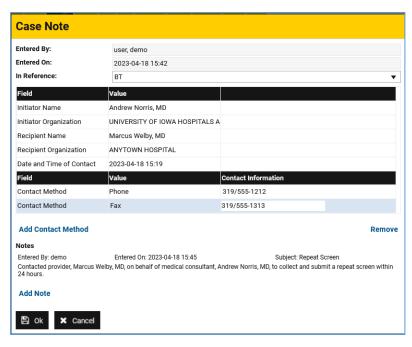


Figure 33 Case Note Pop-up Screen

Entered By

This field displays the name of the logged-in user.

Entered On

This field displays the date and time that the screen was opened.

In Reference

This field defaults to the name of the condition if it is opened from a condition-specific tab. Additional conditions that the case note applies to can be selected. If the screen is opened from the Case History tab, the condition(s) that the case note applies to will need to be selected by the user. The note will be displayed on each condition-specific tab that is selected and on the Case History tab.

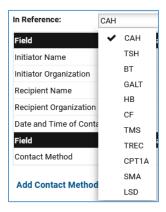


Figure 34 "In Reference" Dropdown List

Initiator Name

This free-text field is used to specify the name of the person who initiated the correspondence/contact.

Initiator Organization

Draft Version 2 2024 Michael B. Hayek 20

This field is used to specify the organization that employs the initiator. This field pulls from the <u>Newborn Contacts</u> module, so the organization must first be entered as a contact into this module.

Recipient Name

This free-text field is used to specify the name of the person who received the correspondence/contact.

Recipient Organization

This field is used to specify the organization that employs the recipient. This field pulls from the <u>Newborn Contacts</u> module, so the organization must first be entered as a contact into this module.

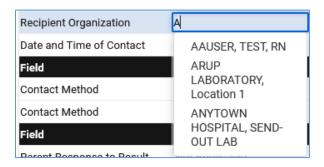


Figure 35 Recipient Organization Autocomplete Dropdown Field

Date and Time of Contact

This field can be used to store the date and time that the contact actually started.

Contact Method

This row can be used to capture the various methods that were used to make the contact. The contact method is selected from the Value dropdown list.

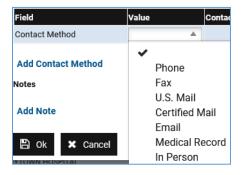


Figure 36 Contact Method Dropdown List

The Contact Information field can be used to capture the specific contact information, such as the phone or fax number, or the mailing or email address of the recipient of the contact.



Figure 37 Multiple Contact Methods with Contact Information

Click the **Add Contact Method** button to add an additional contact method row and the **Remove** button to delete a row.

Notes

Click the Add Note button to add an explanatory note to this screen, if necessary. The Note Editor screen will pop up. A predefined note can be selected from the Standard Note Library. Click on the symbol in front of the name of a category to view the names and descriptions of the standard notes present in that category. Click on a note to view its text in the right pane.

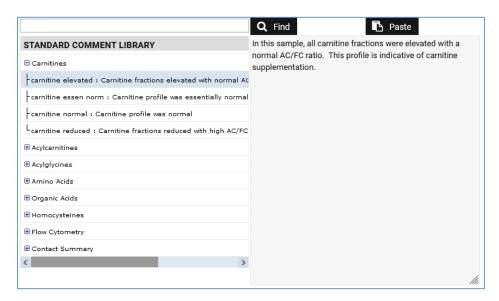


Figure 38 Viewing the text of a Standard Comment

Alternatively, search for standard notes by entering a string of characters in the box in the middle of the screen and clicking the button. Standard notes that have that character string in their name or description will be displayed.

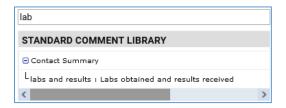


Figure 39 Searching for Standard Comments by a character string

Click the Paste button to copy and paste the text and subject of the standard note to the Note Editor (top pane of the screen).

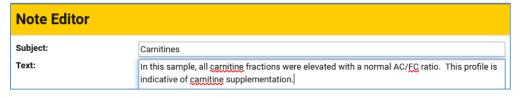


Figure 40 Subject and Text of a note in the Note Editor

The subject and text of the note can be edited in these fields. If an appropriate standard note is not present, the subject and text of the note can be written here.

Click to add the note to the Case Note screen. Additional notes can be added to the screen at any time by clicking the Add Note button.

Next, click to add the case note to the case.

Click on **Update** in the upper right corner of an event to update its information at any time before a case is closed. Exception: Notes that have "Entered By", "Entered On" and "Subject" information cannot be edited at a later time. However, a new note can be added to further explain or clarify a previous note.

Recommendation

This event is added to document any time that a recommendation is made on the case. The fields on this pop-up screen are described below.

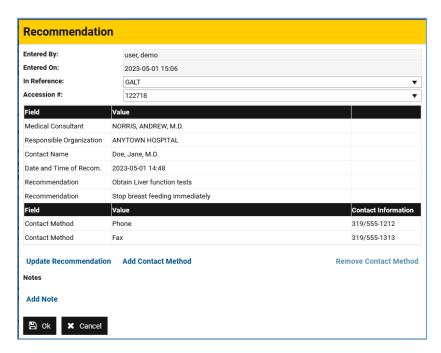


Figure 41 Recommendation Pop-up Screen

Entered By

This field displays the name of the logged-in user.

Entered On

This field displays the date and time that the screen was opened.

In Reference

This field defaults to the name of the condition if it is opened from a condition-specific tab. Additional conditions that the recommendation applies to can be selected. If the screen is opened from the Case History tab, the condition(s) that the recommendation applies to will need to be selected by the user. The recommendation will be displayed on each condition-specific tab that is selected and on the Case History tab.

Accession

The accession number of the relevant newborn screen is selected from this dropdown list.

Medical Consultant

This field is used to specify the medical consultant that made the recommendation. This field pulls from the <u>Newborn</u> Contacts module, so the individual must first be entered as a contact into this module.

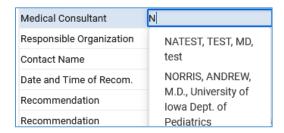


Figure 42 Medical Consultant Autocomplete Dropdown Field

Responsible Organization

This field is used to specify the organization that is responsible for executing the recommendation. This field pulls from the <u>Newborn Contacts</u> module, so the organization must first be entered as a contact into this module.

Contact Name

This free-text field is used to specify the name of the person who received the recommendation.

Date and Time of Recom.

This field can be used to store the actual date and time that the recommendation was made.

Recommendation

This field is used to capture the recommendation that was made. Click the **Update Recommendation** button to add or update a recommendation. The Recommendation Selection screen will pop up.

Click on the symbol in front of the name of a category to view the recommendations that are available for that category. Click the desired recommendation and click the select button. The recommendation will be displayed in the right "Selected Recommendations" pane. Multiple recommendations can be selected from one or multiple categories. Click the Remove button to remove one selected recommendation or the Remove All button to remove all of the selected recommendations.

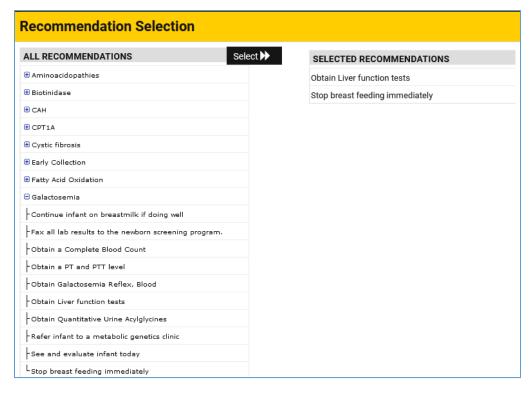


Figure 43 Recommendation Selection Pop-up Screen

Contact Method

This row can be used to capture the various methods that were used to make the recommendation. The <u>contact method</u> is selected from the Value dropdown list.

Click the **Add Contact Method** button to add an additional contact method row and the **Remove Contact Method** button to delete a row.

Notes

Click the **Add Note** button to add an explanatory note to this screen, if necessary. A note is entered using the <u>Note</u> <u>Editor</u> screen as with any other note.

Click to add the note to the Recommendation screen. Additional notes can be added to the screen at any time by clicking the Add Note button.

Next, click to add the recommendation to the case.

Click on **Update** in the upper right corner of an event to update its information at any time before a case is closed. Exception: Notes that have "Entered By", "Entered On" and "Subject" information cannot be edited at a later time. However, a new note can be added to further explain or clarify a previous note.

Recommendation Letter

A recommendation letter template can be downloaded from either a condition-specific tab or the Case History tab, modified as necessary, with the final version of the letter being uploaded as an <u>attachment</u> to the case.

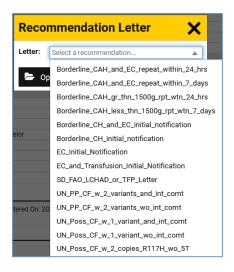


Figure 44 Recommendation Letter Dropdown List

The recommendation letter template needs to be selected from the dropdown list. Click the letter template will be downloaded. It can then be modified as necessary.

Attachment

An attachment can be added to the case from either a condition-specific tab or the Case History tab. Examples of attachments are a <u>recommendation letter</u>, email or mail correspondence, and instrument output. Attachments can be uploaded in any standard file format: .doc, .docx, .pdf, .xls, .xlsx, .txt, .rtf, .csv, etc. The fields on this pop-up screen are described below.

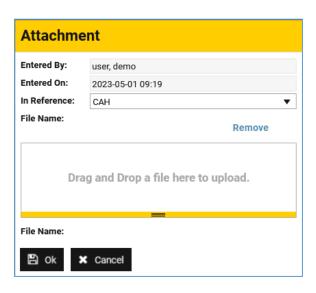


Figure 45 Attachment Pop-up Screen

Entered By

This field displays the name of the logged-in user.

Entered On

This field displays the date and time that the screen was opened.

In Reference

This field defaults to the name of the condition if it is opened from a condition-specific tab. Additional conditions that the attachment applies to can be selected. If the screen is opened from the Case History tab, the condition(s) that the attachment applies to will need to be selected by the user. The attachment will be displayed on each condition-specific tab that is selected and on the Case History tab.

File Name

The file name of the attachment is displayed here.

Drag and Drop

Drag and drop the file into the designated space on this screen. Click the Remove button to remove the file. Click to add the attachment to the case.

Confirmatory Test

This event is added to capture the results and other testing information from a newborn screening confirmatory test. The fields on this pop-up screen are described below.

In Reference

This field defaults to the name of the condition if it is opened from a condition-specific tab. If the screen is opened from the Case History tab, the condition that the confirmatory test applies to will need to be selected by the user. The confirmatory test will be displayed on the condition-specific tab that is selected and on the Case History tab.

Test

The name of the confirmatory test is selected from this dropdown list. The list of tests that are displayed is specific to the condition that was selected in the "In Reference" field.

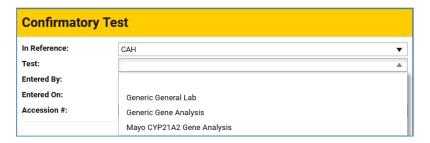


Figure 46 Confirmatory Test Name Dropdown List

Entered By

This field displays the name of the logged-in user.

Entered On

This field displays the date and time that the screen was opened.

Accession

The accession number of the relevant newborn screen is selected from this dropdown list.

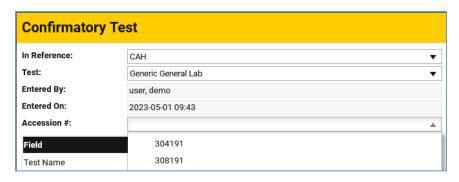


Figure 47 Confirmatory Test Accession # Dropdown List

Test Name

This free-text field is normally only present if a "generic" <u>Test</u> is selected. It allows the user to enter the exact name of the test.

Performing Organization

This free-text field allows the user to enter the name of the organization that performed the confirmatory test.

Reviewing Physician

This field is used to specify the medical consultant that reviewed the results of this test. This field pulls from the Newborn Contacts module, so the individual must first be entered as a contact into this module.

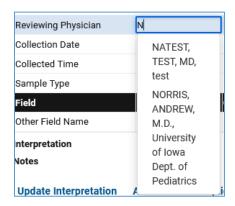


Figure 48 Reviewing Physician Autocomplete Dropdown Field

Collection Date

This field can be used to store the date that the sample for the confirmatory test was collected.

Collected Time

This field can be used to store the time that the sample for the confirmatory test was collected, if known.

Sample Type

This dropdown list or free-text field can be used to capture the sample type of the specimen. If there is only one acceptable sample type for the test, it will be selected by default.

Result

This dropdown field may be present depending upon the confirmatory test that is selected. It allows for a standard result to be captured, such as Positive, Negative, or Other.

Draft Version 2 2024 Michael B. Hayek 28

Other Analytes and Values

There may be other analytes and values that are displayed depending upon the test that is selected. Some of these fields are predefined and some are free text. These fields could include units of measurement and reference ranges.

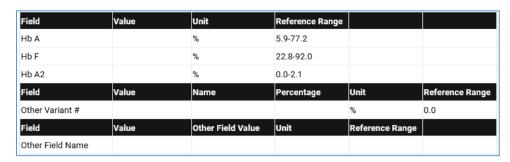


Figure 49 Confirmatory Test with Some Predefined Fields

A field row can be duplicated using the **Duplicate Field** button. A field row can be removed using the **Remove Field** button.

Interpretation

The interpretation of the results of the confirmatory test can be added to this field. Click the **Update Interpretation** button to add or update the interpretation. An interpretation is entered using the <u>Note Editor</u> screen as with other notes. The only differences between the way that an interpretation and a note work are that an interpretation will not have "Entered By", "Entered On" and "Subject" information and it can be edited at a later time.

Notes

Click the **Add Note** button to add an explanatory note to this screen, if necessary. A note is entered using the <u>Note</u> Editor screen as with any other note.

Click to add the note to the Confirmatory Test screen. Additional notes can be added to the screen at any time by clicking the Add Note button.

Next, click to add the confirmatory test to the case.

Click on **Update** in the upper right corner of an event to update its information at any time before a case is closed. Exception: Notes that have "Entered By", "Entered On" and "Subject" information cannot be edited at a later time. However, a new note can be added to further explain or clarify a previous note.

Family Contact Call

The Family Contact Call screen can be used to document contact made to the family of the patient by a genetic counselor. The fields on this pop-up screen are described below.

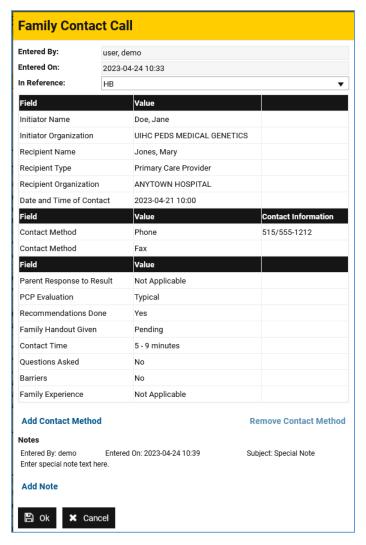


Figure 50 Family Contact Call Pop-up Screen

Entered By

This field displays the name of the logged-in user.

Entered On

This field displays the date and time that the screen was opened.

In Reference

This field defaults to the name of the condition if it is opened from a condition-specific tab. Additional conditions that the family contact call applies to can be selected. If the screen is opened from the Case History tab, the condition(s) that the family contact call applies to will need to be selected by the user. The family contact call will be displayed on each condition-specific tab that is selected and on the Case History tab.

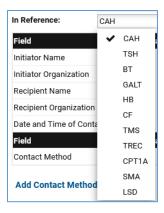


Figure 51 "In Reference" Dropdown List

Initiator Name

This free-text field is used to specify the name of the person who initiated the family contact call. This would normally be a genetic counselor.

Initiator Organization

This field is used to specify the organization that employs the initiator. This field pulls from the <u>Newborn Contacts</u> module, so the organization must first be entered as a contact into this module.

Recipient Name

This free-text field is used to specify the name of the person who received the family contact call.

Recipient Type

The type of recipient of the family contact call can be selected from a dropdown list.

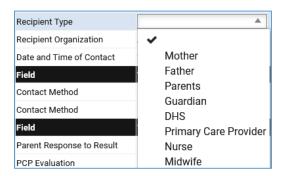


Figure 52 Recipient Type Dropdown Field

Recipient Organization

This field is used to specify the organization that employs the recipient (if applicable). This field pulls from the <u>Newborn</u> <u>Contacts</u> module, so the organization must first be entered as a contact into this module.

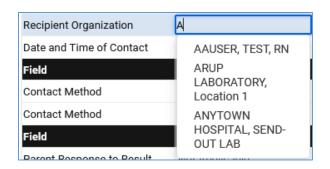


Figure 53 Recipient Organization Autocomplete Dropdown Field

Date and Time of Contact

This field can be used to store the date and time that the family contact call started.

Contact Method

This row can be used to capture the various methods that were used to make the family contact call. The contact method is selected from the Value dropdown list.

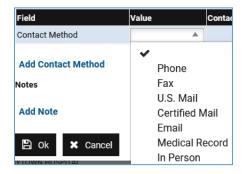


Figure 54 Contact Method Dropdown List

The Contact Information field can be used to capture the specific contact information, such as the phone or fax number, or the mailing or email address of the recipient of the family contact call.



Figure 55 Multiple Contact Methods with Contact Information

Click the **Add Contact Method** button to add an additional contact method row and the **Remove** button to delete a row.

Parent Response to Result

The parent's response to the genetic counseling result (if applicable) can be captured in this dropdown field.

PCP Evaluation

The evaluation of the primary care provider by the genetic counselor (if applicable) can be captured in this dropdown field.

Recommendations Done

Draft Version 2 2024 Michael B. Hayek 32

Whether recommendations have been made by the genetic counselor can be captured in this dropdown field.

Family Handout Given

Whether the family handout has been provided to the family can be captured in this dropdown field.

Contact Time

The length of the family contact call can be captured in this dropdown field.

Questions Asked

Whether questions were asked by the recipient can be captured in this dropdown field.

Barriers

Whether any barriers are present can be captured in this dropdown field.

Family Experience

The patient's family experience (if applicable) can be captured in this dropdown field.

Notes

Click the Add Note button to add an explanatory note to this screen, if necessary. The Note Editor screen will pop up. A predefined note can be selected from the Standard Comment Library. Click on the symbol in front of the name of a category to view the names and descriptions of the standard notes present in that category. Click on a note to view its text in the right pane.

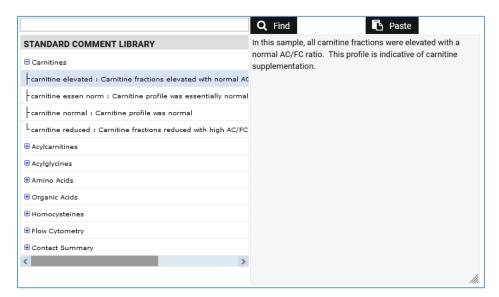


Figure 56 Viewing the text of a Standard Comment

Alternatively, search for standard notes by entering a string of characters in the box in the middle of the screen and clicking the button. Standard notes that have that character string in their name or description will be displayed.

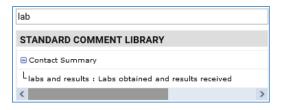


Figure 57 Searching for Standard Comments by a character string

Click the Paste button to copy and paste the text and subject of the standard note to the Note Editor (top pane of the screen).

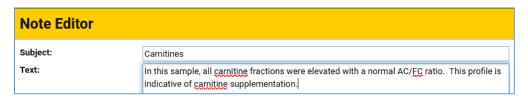


Figure 58 Subject and Text of a note in the Note Editor

The subject and text of the note can be edited in these fields. If an appropriate standard note is not present, the subject and text of the note can be written here.

Click to add the note to the Family Contact Call screen. Additional notes can be added to the screen at any time by clicking the **Add Note** button.

Next, click to add the Family Contact Call event to the case.

Click on **Update** in the upper right corner of an event to update its information at any time.

Exception: Notes that have "Entered By", "Entered On" and "Subject" information cannot be edited at a later time. However, a new note can be added to further explain or clarify a previous note.

Genetic Counseling

The Genetic Counseling screen can be used to document a genetic counseling session for the guardian/family of a patient. The fields on this pop-up screen are described below.

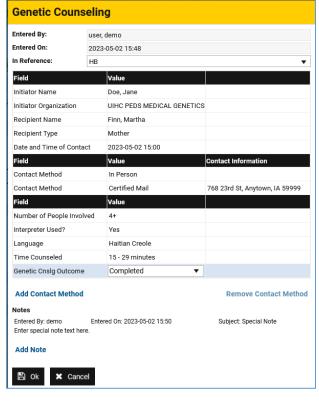


Figure 59 Genetic Counseling Pop-up Screen

Entered By

This field displays the name of the logged-in user.

Entered On

This field displays the date and time that the screen was opened.

In Reference

This field defaults to the name of the condition if it is opened from a condition-specific tab. Additional conditions that the genetic counseling event applies to can be selected. If the screen is opened from the Case History tab, the condition(s) that the genetic counseling event applies to will need to be selected by the user. The Genetic Counseling event will be displayed on each condition-specific tab that is selected and on the Case History tab.

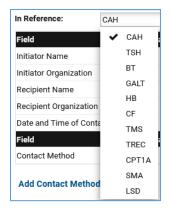


Figure 60 "In Reference" Dropdown List

Initiator Name

This free-text field is used to specify the name of the person who performed the genetic counseling. This would normally be a genetic counselor.

Initiator Organization

This field is used to specify the organization that employs the initiator. This field pulls from the <u>Newborn Contacts</u> module, so the organization must first be entered as a contact into this module.

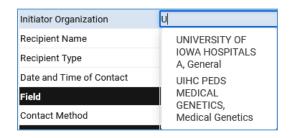


Figure 61 Initiator Organization Autocomplete Dropdown Field

Recipient Name

This free-text field is used to specify the name(s) of the person(s) who received the genetic counseling.

Recipient Type

The type of recipient of the genetic counseling can be selected from a dropdown list.

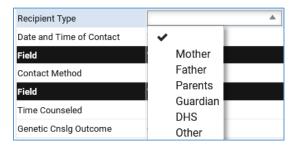


Figure 62 Recipient Type Dropdown Field

Date and Time of Contact

This field can be used to store the date and time that the genetic counseling session started.

Contact Method

This row can be used to capture the various methods that were used for the genetic counseling session. The contact method is selected from the Value dropdown list.

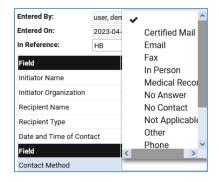


Figure 63 Contact Method Dropdown List

The Contact Information field can be used to capture the specific contact information, such as the phone or fax number, or the mailing or email address of the recipient of the genetic counseling.



Figure 64 Multiple Contact Methods with Contact Information

Click the **Add Contact Method** button to add an additional contact method row and the **Remove Contact Method** button to delete a row.

Number of People Involved

The number of people involved in the genetic counseling session can be captured in this dropdown field.

Interpreter Used?

Whether an interpreter was used in the genetic counseling session can be captured in this dropdown field.

Language

The language that was interpreted in the genetic counseling session (if applicable) can be captured in this dropdown field.

Time Counseled

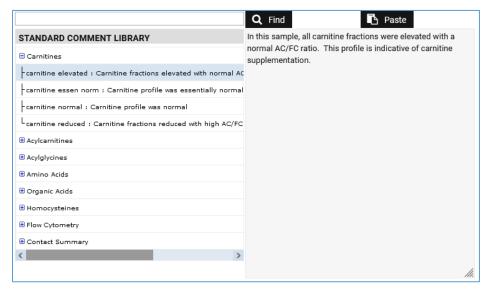
The length of the genetic counseling session can be captured in this dropdown field.

Genetic Cnslg Outcome

The outcome of genetic counseling can be captured in this dropdown field.

Notes

Click the Add Note button to add an explanatory note to this screen, if necessary. The Note Editor screen will pop up. A predefined note can be selected from the Standard Comment Library. Click on the symbol in front of the name of a category to view the names and descriptions of the standard notes present in that category. Click on a note to view its text in the right pane.



Alternatively, search for standard notes by entering a string of characters in the box in the middle of the screen and clicking the button. Standard notes that have that character string in their name or description will be displayed.

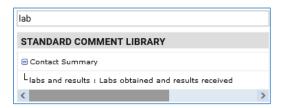


Figure 66 Searching for Standard Comments by a character string

Click the Paste button to copy and paste the text and subject of the standard note to the Note Editor (top pane of the screen).

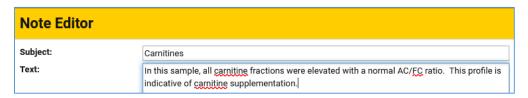


Figure 67 Subject and Text of a note in the Note Editor

The subject and text of the note can be edited in these fields. If an appropriate standard note is not present, the subject and text of the note can be written here.

Click to add the note to the Genetic Counseling screen. Additional notes can be added to the screen at any time by clicking the Add Note button.

Next, click to add the Genetic Counseling event to the case.

Click on **Update** in the upper right corner of an event to update its information at any time. Exception: Notes that have "Entered By", "Entered On" and "Subject" information cannot be edited at a later time. However, a new note can be added to further explain or clarify a previous note.

Condition Short-Term Outcome

This event is added to document any time that a short-term outcome is assigned to a condition. Prerequisites include: the case is open and there isn't already a short-term outcome added for the condition. The fields on this pop-up screen are described below.

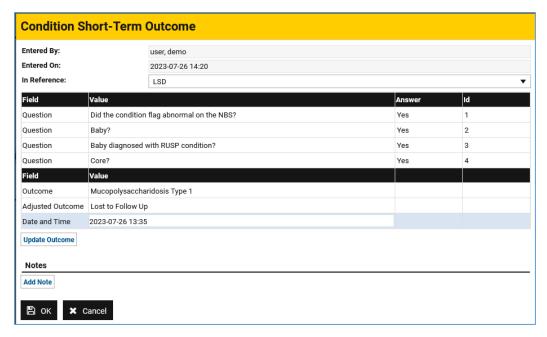


Figure 68 Condition Short-Term Outcome Pop-up Screen

Entered By

This field displays the name of the logged-in user.

Entered On

This field displays the date and time that the screen was opened.

In Reference

This field defaults to the name of the condition if it is opened from a condition-specific tab. Additional conditions that the short-term outcome applies to can be selected. If the screen is opened from the Case History tab, the condition(s) that the short-term outcome applies to will need to be selected by the user. The short-term outcome will be displayed on each condition-specific tab that is selected and on the Case History tab.

Questions and Answers Table

The "Questions and Answers" table is populated by the user's answers to predefined questions that are part of a newborn screening outcomes decision tree. The order of the questions that were asked is shown in the Id column. Click

on the Update Outcome button to complete or update this table. The Condition Outcome Selection screen will pop up. Select the answer to each question. The next question will then be displayed based on the answer to the previous question. The series of questions and answers will narrow down the choices of possible outcomes. The user will select the short-term outcome for the condition with the last question.

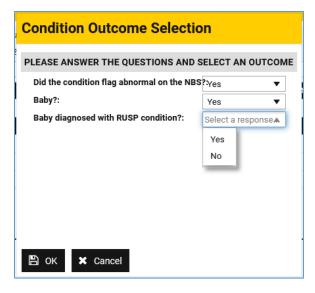


Figure 69 Condition Outcome Selection Pop-up Screen

Outcome

The condition short-term outcome that was selected is displayed in this field.

Adjusted Outcome

This optional field is used to specify the adjusted short-term outcome for the condition based upon additional case information that is available at that time.

Date and Time

This field can be used to store the date and time that the condition short-term outcome was actually assigned.

Notes

Click the Add Note button to add an explanatory note to this screen, if necessary. A note is entered using the Note Editor screen as with any other note.

Click to add the note to the Condition Short-Term Outcome screen. Additional notes can be added to the screen at any time by clicking the **Add Note** button.

Next, click to add the short-term outcome to the condition.

Click on **Update** in the upper right corner of an event to update its information at any time before a case is closed. Exception: Notes that have "Entered By", "Entered On" and "Subject" information cannot be edited at a later time. However, a new note can be added to further explain or clarify a previous note.

Condition Long-Term Outcome

This event is currently disabled.

This event is added to document the long-term outcome for a condition. The fields on this pop-up screen are described below.

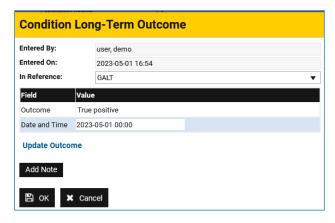


Figure 70 Condition Long-Term Outcome Pop-up Screen

Entered By

This field displays the name of the logged-in user.

Entered On

This field displays the date and time that the screen was opened.

In Reference

This field defaults to the name of the condition if it is opened from a condition-specific tab. If the screen is opened from the Case History tab, the condition that the long-term outcome applies to will need to be selected by the user. The long-term outcome will be displayed on both the condition-specific tab that is selected and on the Case History tab.

Outcome

This dropdown field is used to capture the long-term outcome of the condition.

Date and Time

This field can be used to store the date and time that the condition long-term outcome was actually assigned.

Notes

Click the **Add Note** button to add an explanatory note to this screen, if necessary. A note is entered using the <u>Note</u> <u>Editor</u> screen as with any other note.

Click to add the note to the Condition Long-Term Outcome screen. Additional notes can be added to the screen at any time by clicking the Add Note button.

Next, click to add the long-term outcome to the condition.

Click on **Update** in the upper right corner of a Condition Long-Term Outcome event to update its information at any time. Exception: Notes that have "Entered By", "Entered On" and "Subject" information cannot be edited at a later time. However, a new note can be added to further explain or clarify a previous note.

Case Outcome

This event is added to document the outcome on the entire case. Prerequisites include: the case is open and there isn't already a case outcome added for the case. The fields on this pop-up screen are described below.

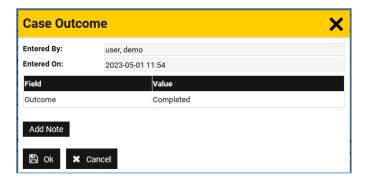


Figure 71 Case Outcome Pop-up Screen

Entered By

This field displays the name of the logged-in user.

Entered On

This field displays the date and time that the screen was opened.

Outcome

This dropdown field is used to capture the outcome of the entire case.

Notes

Click the Add Note button to add an explanatory note to this screen, if necessary. A note is entered using the Note Editor screen as with any other note.

Click to add the note to the Case Outcome screen. Additional notes can be added to the screen at any time by clicking the Add Note button.

Next, click to add the case outcome to the case.

Click on **Update** in the upper right corner of an event to update its information at any time before a case is closed. Exception: Notes that have "Entered By", "Entered On" and "Subject" information cannot be edited at a later time. However, a new note can be added to further explain or clarify a previous note.

Ready To Close Cases

When the casework is finished, the case will be displayed in a table on the Ready to Close Cases tab of the Newborn Follow-Up module. Prerequisites include:

- 1. The case is open.
- 2. All conditions with an abnormal result have a condition short-term outcome assigned.
- 3. All tags are closed.
- 4. A case outcome has been added.

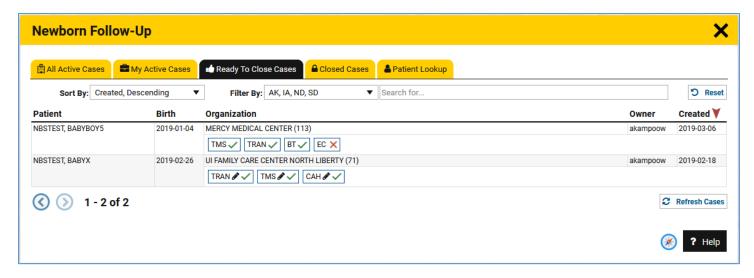


Figure 72 Ready To Close Cases Tab

These cases can be <u>sorted</u>, <u>filtered</u>, <u>and searched</u> using the same tools that are present on the All Active Cases and My Active Cases tabs.

The buttons are used to page through the cases. The cases that are displayed can be updated in real time by clicking the Refresh Cases button.

The case table fields were described previously. Click on a patient row to view the case details.

Go to the <u>Case History</u> tab and review the entire case. Click the <u>Dropdown Menu</u> to close the case. Click "OK" on the confirmation message.



Figure 73 Close Case Confirmation Question

Closed Cases

Closed cases can be queried and displayed through the Closed Cases tab of the Newborn Follow-Up module. Certain event types can be added to a closed case. A case can also be reopened if needed.

Query Fields

The query fields of this tab are described below.

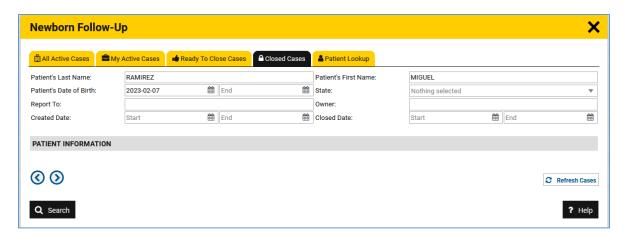


Figure 74 Closed Cases Tab - Searching by Patient's Last Name, First Name, and Date of Birth

Patient's Last Name, Patient's First Name

Cases can be searched by the last name and/or first name of the patient. The system supports wild card searches in the Patient's Last Name and Patient's First Name fields. To use this search method, add an * at the beginning and/or end of the search term.

For example, to see a list of cases for a patient whose last name starts with the letters "SCHM", enter SCHM* in the Patient's Last Name field. Matches would include SCHMIDT, SCHMITT, SCHMITZ, etc.

To see a list of samples for a patient whose first name ends with the letters "JO", enter *JO in the Patient's First Name field. Matches would include BETTY JO, BOBBY JO, BETTYJO, JO, etc.

Patient's Date of Birth

Cases can be searched by entering the patient's date of birth in the "Start" field. To search by a range of dates enter a Start date and an End date.

It is recommended to click in a date field and use the calendar when entering a date to eliminate any formatting errors. Click on the word "TODAY" at the bottom of the calendar to insert the current date. Dates can also be typed. All dates have the format of YYYY-MM-DD.

State

Cases can be restricted to one or more states through this dropdown field. It can be used to limit the cases to a specific state for users who have permissions to multiple states.

Report To

Cases can be searched by the name of the "Report To" organization that was linked to the initial newborn screening sample for the patient. Results are reported to the "Report To" organization through mail, the OpenELIS Web Portal, and/or an electronic results interface. The system supports wild card searches in this field.

Owner

Cases can be searched by the username of the case owner. The system supports wild card searches in this field.

Created Date

Cases can be queried by the date that the case was created in the "Start" field. To search by a range of dates enter a Start date and an End date. All dates have the format of YYYY-MM-DD.

Closed Date

Cases can be queried by the date that the case was closed in the "Start" field. To search by a range of dates enter a Start date and an End date. All dates have the format of YYYY-MM-DD.

Click the Search button to query for samples that meet the search criteria.

Patient Information Table

The cases that meet the search criteria will be displayed at the bottom of the screen in a table. The buttons are used to page through these cases. The Refresh Cases button is used to refresh the list of cases in real time. The table columns are described below.

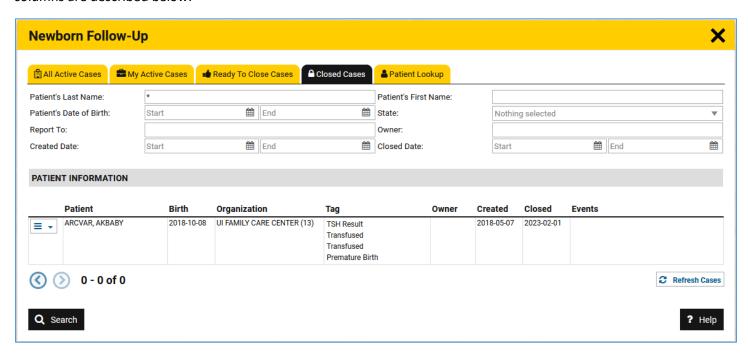


Figure 75 Closed Cases Tab – Patient Information Table

Patient

The last name, first name of the newborn is displayed in this column.

Birth

The birth date of the newborn is displayed here.

Organization

The name and OpenELIS id of the "Report To" organization that is linked to the initial newborn screening sample is displayed here. Results are reported to the "Report To" organization through mail, the OpenELIS Web Portal, and/or an electronic results interface.

Tag

Any <u>tags</u> that are present on a case are displayed in this column. Tags are used to remind the user as to when a specific action needs to be undertaken.

Owner

The username of the owner of the case is displayed here.

Created

The date that the case was created is displayed in this column.

Closed

The date that the case was closed is displayed in this column.

Events

The types of <u>events</u> that were added to the case are displayed here.

Select "View case" on the dropdown button to view the <u>Case Details</u> screen. The date that the case was closed is displayed along with its creation date in the screen header.

Case Details - TEST, BABY - Created (2018-05-07), Closed (2023-02-01)

Figure 76 Date Case Closed Displayed on Case Details Screen

Select "Add case event" on the dropdown button to go to the <u>Case History</u> tab of the Case Details screen. Only certain event types can be added to a closed case: Family Contact Call, Genetic Counseling, and Condition Long-Term Outcome.

Reopen a Case

Occasionally, a case needs to be reopened to add or correct information or an event. The only prerequisite is that the case is currently closed. A case does not need to and should not be reopened to add a Family Contact Call, Genetic Counseling, or Condition Long-Term Outcome event.

Select "Open Case" on the dropdown button to reopen a case. The system will ask the user to confirm that the case should be opened. Click "OK".



Figure 77 Open Case Confirmation Question

The system will confirm that the case was opened. Click "OK".

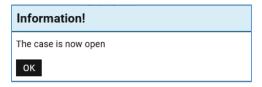


Figure 78 Open Case Confirmation

Patient Lookup

The Patient Lookup tab of the Newborn Follow-Up module can be used to search for any newborn screening patients that were tested by the laboratory regardless of whether a case was initiated on that patient. A final report can be generated for each of a patient's newborn screening samples and a sentinel event can be created on a patient, if necessary.

Query Fields

The query fields of this tab are described below.

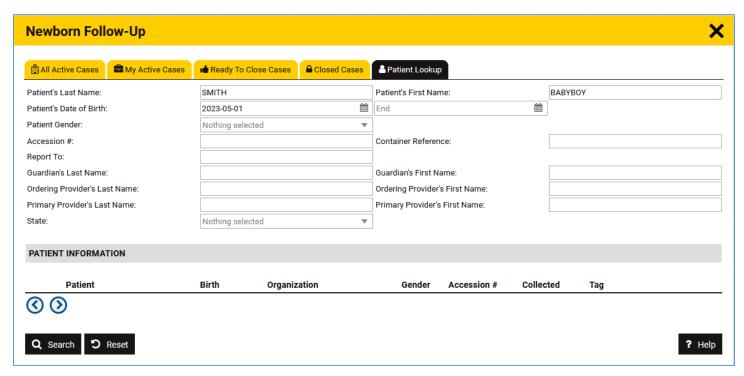


Figure 79 Patient Lookup Tab - Searching by Patient's Last Name, First Name, and Date of Birth

Patient's Last Name, Patient's First Name

Patients can be searched by the last name and/or first name of the patient. The system supports wild card searches in these fields. To use this search method, add an * at the beginning and/or end of the search term.

For example, to see a list of patients whose last name starts with the letters "SCHM", enter SCHM* in the Patient's Last Name field. Matches would include SCHMIDT, SCHMITT, SCHMITT, etc.

To see a list of patients whose first name ends with the letters "JO", enter *JO in the Patient's First Name field. Matches would include BETTY JO, BOBBY JO, BETTYJO, JO, etc.

Patient's Date of Birth

Patients can be searched by entering the patient's date of birth in the "Start" field. To search by a range of dates enter a Start date and an End date.

It is recommended to click in a date field and use the calendar when entering a date to eliminate any formatting errors. Click on the word "TODAY" at the bottom of the calendar to insert the current date. Dates can also be typed. All dates have the format of YYYY-MM-DD.

Patient Gender

Patients can be searched by their assigned sex at birth as provided to the laboratory. Options are Female, Male, and Unknown.

Accession

Patients can be searched by the number (id) assigned to any of their newborn screening samples by the performing laboratory. The system supports wild card searches in this field.

Container Reference

Patients can be searched by the container reference of any of their newborn screening samples. The container reference can be used to store the serial number of a newborn screening dried blood spot collection card. The system supports wild card searches in this field.

Report To

Patients can be searched by the name of the "Report To" organization of any of their newborn screening samples. Results are reported to the "Report To" organization through mail, the OpenELIS Web Portal, and/or an electronic results interface. The system supports wild card searches in this field.

Guardian's Last Name, Guardian's First Name

Patients can be searched by the last name and/or first name of their guardian. The system supports wild card searches in these fields.

Ordering Provider's Last Name, Ordering Provider's First Name

Patients can be searched by the last name and/or first name of the ordering provider of any of their newborn screening samples. The system supports wild card searches in these fields.

Primary Provider's Last Name, Primary Provider's First Name

Patients can be searched by the last name and/or first name of the primary care provider listed on any of their newborn screening samples. The system supports wild card searches in these fields.

State

Patients can be restricted to one or more states through this dropdown field. It can be used to limit the patients to a specific state for users who have permissions to multiple states.

Click the button to query for patients that meet the search criteria. Click the button to clear the search fields.

Patient Information Table

The patients that meet the search criteria will be displayed at the bottom of the tab in a table. The table columns are described below.

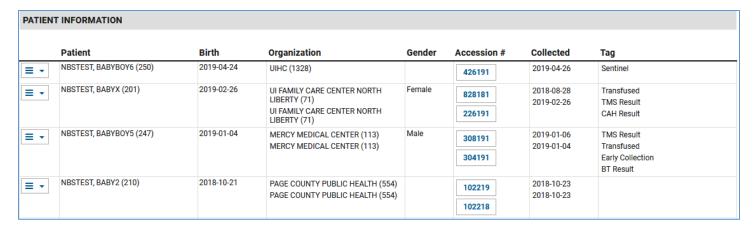


Figure 80 Patient Lookup Tab - Patient Information Table

Patient

The patient's last name, first name, and unique OpenELIS id is displayed in this column.

Birth

The birth date of the newborn is displayed here.

Organization

The name(s) and OpenELIS id(s) of the "Report To" organization(s) of the newborn screening sample(s) are displayed here. Results are reported to the "Report To" organization through mail, the OpenELIS Web Portal, and/or an electronic results interface.

Gender

The assigned sex at birth of the patient as provided to the laboratory is displayed in this column. Options are Female, Male, and Unknown.

Accession

The numbers (ids) of any newborn screening samples for the patient are displayed here as a blue link. Click on the link to pop up a PDF of the final report for that sample.

Collected

The date(s) that the patient's newborn screening sample(s) were collected are displayed in the format of YYYY-MM-DD.

Tag

Any <u>tags</u> that are present on a case are displayed in this column. Tags are used to remind the user as to when a specific action needs to be undertaken.

Select "View case" on the dorpdown button to view the <u>Case Details</u> screen. The date that the case was created is displayed in the screen header along with its closed date, if applicable.

Select "Add case event" on the dropdown button to go to the <u>Case History</u> tab of the Case Details screen. Add an event to the case by selecting it from the <u>Case event dropdown menu</u>. Only certain event types can be added to a closed case: Family Contact Call, Genetic Counseling, and Condition Long-Term Outcome.

Select "Create Sentinel Event" on the \Box dropdown button to initiate a case on a patient by adding a case event. The system will ask the user to confirm the creation of a sentinel event on the patient. Click "OK".

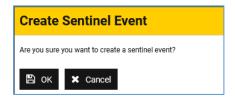


Figure 81 Sentinel Event Creation Confirmation Question

The system will confirm that a sentinel event was created for the patient. Click "OK".

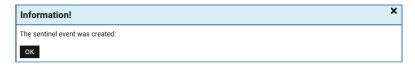


Figure 82 Sentinel Event Creation Confirmation

A "Sentinel" tag will then be displayed in the Tag column of that patient.

Newborn Contacts Module

The **Newborn Contacts** module is used to add the names and contact information of both individuals and organizations to the <u>Newborn Follow-Up</u> module. Existing contacts can also be queried from this module. Click on the <u>Newborn Contacts button</u> or the link in the <u>Follow-Up menu</u> to open this module.

Querying for Existing Contacts

Information only needs to be entered into one field to conduct a search for contacts. Querying by multiple fields will further narrow the search. The query fields are described below.

Click on the Tool Tip ? to the right of each field to view information about the use and format of that field.

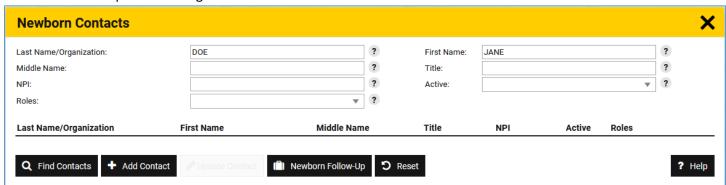


Figure 83 Newborn Contacts Module - Querying by a Person's Last Name and First Name

Last Name/Organization, First Name, Middle Name

Individuals can be searched by the last name, first name, and/or middle name of the person. Organizations can be searched by the Last Name/Organization field. The system supports wild card searches in these fields. To use this search method, add an * at the beginning and/or end of the search term.

For example, to see a list of contacts whose last name/organization name starts with the letters "SCHM", enter SCHM* in the Last Name/Organization field. Matches would include SCHMIDT, SCHMITT, SCHMITZ, SCHMIDT MEDICAL CENTER, etc.

Draft Version 2 2024 Michael B. Hayek 50

To see a list of contacts for individuals whose first name ends with the letters "JO", enter *JO in the First Name field. Matches would include BETTY JO, BOBBY JO, BETTYJO, JO, etc.

Title

Individuals can be searched by their job title. The system supports wild card searches in this field.

NPI

Individuals can be searched by their National Provider Identifier (NPI). The NPI is a unique identification number for covered health care providers. Covered health care providers and all health plans and health care clearinghouses must use the NPIs in the administrative and financial transactions adopted under HIPAA. The NPI is a 10-position, intelligence-free numeric identifier (10-digit number). The system supports wild card searches in this field.

Active

A search can be restricted to active or inactive contacts by selecting "YES" or "NO" from this dropdown field. If this field is left empty, both active and inactive contacts will be displayed.

Roles

A contact search can be restricted to one or more roles by selecting them from this dropdown field. If this field is left empty, contacts assigned any role will be displayed. A contact can be assigned multiple roles, if necessary.

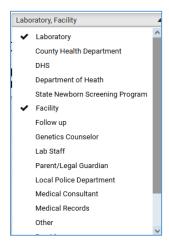


Figure 84 Newborn Contacts Roles Dropdown List

After entering the search parameters, click the the search fields.

Q Find Contacts button to query. Click the



The contacts that meet the search criteria will be displayed at the bottom of the screen in a table. The columns of the table are the same as the <u>query fields</u> that are described above.

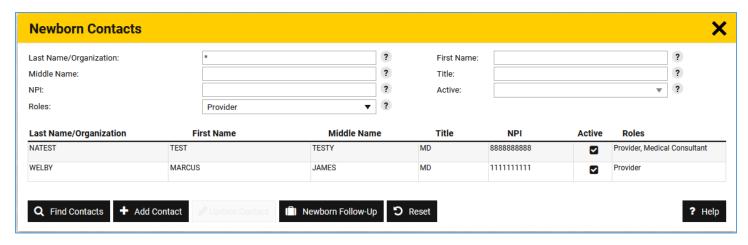


Figure 85 Newborn Contacts Query Results

Adding or Updating a Contact

Click the Add Contact button to add a new contact. The **Newborn Contact** screen will pop up.

The fields on the Newborn Contact pop-up screen are the same as the <u>query fields</u> that are described above with the addition of the contact's location information, if present. Click the **Add Location** button to add a location row. Click the **Remove** button to remove a location row. The number of roles that have been selected for the contact is displayed in parentheses after the word "ROLES". Click

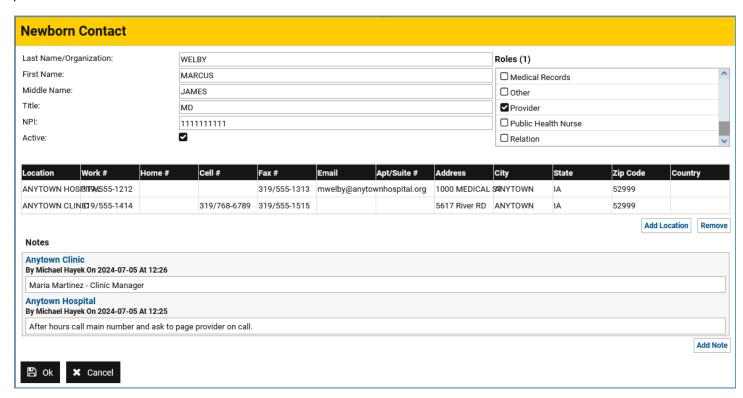


Figure 86 Newborn Contact Pop-up Screen

Select a contact row in the bottom table of the Newborn Contacts screen to view its location information or update any of its information. The Update Contact button will become unhidden. Click this button. The Newborn Contact screen will pop up. Update the contact's information, if necessary, and click to save the changes.

Draft Version 2 2024 Michael B. Hayek 52

Notes

Click the Add Note button to add an explanatory note to the Newborn Contact pop-up screen, if necessary. A note is entered using the Note Editor screen as with any other note.

Click to add the note to the **Newborn Contact** pop-up screen. Additional notes can be added to the screen at any time by clicking the **Add Note** button. Notes that have "Entered By", "Entered On" and "Subject" information cannot be edited at a later time. However, a new note can be added to further explain or clarify a previous note.

Click the Newborn Follow-Up button to navigate to the Newborn Follow-Up module.

Monitor Patients

The Monitor Patients screen is used by dieticians to monitor the results of periodic testing for Phenylketonuria (PKU) and Maple Syrup Urine Disease (MSUD) among children and young adults. Click on the **Monitor Patients** button (or select it from the Other menu).

Information only needs to be entered into one field to conduct a search for monitoring samples. Example fields include **Analysis Released Date**, **Patient's Last Name**, or **Patient's First Name**. Querying by multiple fields will further narrow the search. The guery fields are described below.

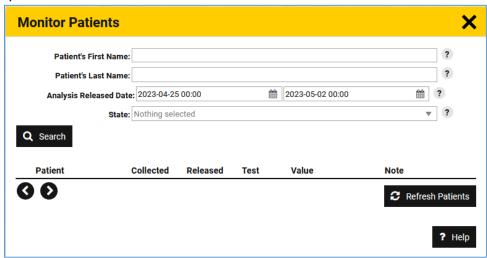


Figure 87 Monitor Patients Screen – Querying by an Analysis Released Date and Time Range

Patient's Last Name, Patient's First Name

Samples can be searched by the last name and/or first name of the patient. The system supports wild card searches in the Patient's Last Name and Patient's First Name fields. To use this search method, add an * at the beginning and/or end of the search term.

For example, to see a list of samples for a patient whose last name starts with the letters "SCHM", enter SCHM* in the Patient's Last Name field. Matches would include SCHMIDT, SCHMITT, SCHMITZ, etc.

To see a list of samples for a patient whose first name ends with the letters "JO", enter *JO in the Patient's First Name field. Matches would include BETTY JO, BOBBY JO, BETTYJO, JO, etc.

Analysis Released Date

Samples can be searched by a date and time range of when their test results were released. To search by a range of dates enter a Start date and an End date.

It is recommended to click in a date field and use the calendar when entering a date to eliminate any formatting errors. Click on the word "TODAY" at the bottom of the calendar to insert the current date and time. Dates and times can also be typed. Analysis Released Date has the format of YYYY-MM-DD HH:MM.

State

Samples can be restricted to one or more states through this dropdown field. It can be used to limit the samples to a specific state for users who have permissions to multiple states.

Click the Search button to query for samples that meet the search criteria.

The samples that meet the search criteria will be displayed at the bottom of the screen in a table. The buttons are used to page through these samples. The Refresh Patients button is used to refresh the list of samples in real time. The table columns are described below.

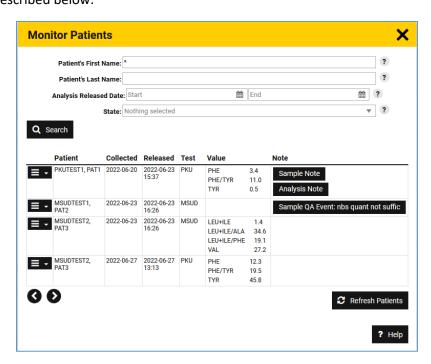


Figure 88 Monitor Patients Screen – Sample Table

Patient

The Patient's Last Name, Patient's First Name is displayed in this column.

Collected

The date that the sample was collected is displayed in the format of YYYY-MM-DD.

Released

The date and time that the results of the analysis (test) were released is displayed in the format of YYYY-MM-DD HH:MM.

Test

The name of the test that was performed is displayed here, either PKU or MSUD.

Value

The analyte names and their values are displayed in this column. Values are either in mg/dL or a ratio.

Note

This column notifies the user if any sample-level and analysis-level external notes and quality assurance (QA) events are present. Click on a black rectangle to pop up the text of the note or QA event.

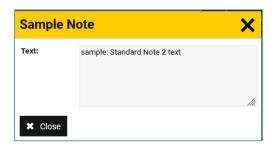


Figure 89 Sample Note Pop-up Screen

Click on the dropdown button before a patient name and select "View patient record" to view all of the test results and sample data for that patient. The Monitor History screen will pop up. The columns on this screen are described below.

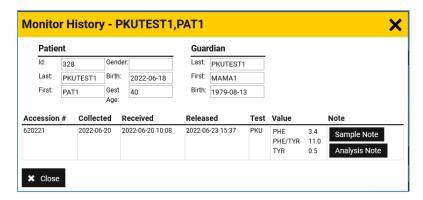


Figure 90 Monitor History Pop-up Screen

Patient Id

The unique id of the patient as automatically assigned by OpenELIS.

Patient Last

The last name of the patient as provided to the laboratory.

Patient First

The first name of the patient as provided to the laboratory.

Patient Gender

The assigned sex at birth of the patient as provided to the laboratory. Options are Female, Male, and Unknown.

Patient Birth

The birth date of the patient as provided to the laboratory.

Patient Gest(ational) Age

This is the common term used during pregnancy to describe how far along the pregnancy was at birth. It is measured in weeks, from the first day of the woman's last menstrual cycle to the newborn's birth date. The value of the gestational age of the patient will only be provided if the newborn screen of the patient was performed by the laboratory in OpenELIS.

Guardian Last

The last name of the patient's guardian is displayed in this field, if provided. The value of the guardian's last name, first name, and birth date will only be provided if the newborn screen of the patient was performed by the laboratory in OpenELIS.

Guardian First

The first name of the patient's guardian is shown here, if provided.

Guardian Birth

The birth date of the patient's guardian is shown here, if provided.

Accession

The number (id) assigned to the sample by the performing laboratory.

Collected

The date that the sample was collected is displayed in the format of YYYY-MM-DD.

Received

The date and time that the sample was received at the performing laboratory is displayed in the format of YYYY-MM-DD HH:MM.

Released

The date and time that the results of the analysis (test) were released is displayed in the format of YYYY-MM-DD HH:MM.

Test

The name of the test that was performed is displayed here, either PKU or MSUD.

Value

The analyte names and their values are displayed in this column. Values are either in mg/dL or a ratio.

Note

This column notifies the user if any sample-level and analysis-level external notes and quality assurance (QA) events are present. Click on a black rectangle to pop up the text of the note or QA event.

General Reports

Final Report Statewide Screen

The Final Report Statewide screen allows the user to search for and download the final reports for a particular sample domain(s) for samples that were submitted by organizations anywhere in a state or for patients that reside in a specified state. For instance, the user may have permissions to search for and download the final reports for any newborn screening samples submitted to the laboratory for patients that reside in a specified state.

Click on the Final Report Statewide button (or select it from the General Reports menu).

Query Fields

Information only needs to be entered in one field to conduct a search for samples. Example fields include **Collected Date**, **Released Date**, **Accession Number**, **Client Reference**, or **Patient's Last Name**.

It is recommended to click in a date field and use the calendar when entering a date to eliminate any formatting errors. Clicking on the word "TODAY" at the bottom of the calendar will insert the current date (or date and time). Dates can also be typed, if preferred. All dates have the format of YYYY-MM-DD. **Released Date** also includes the time in the format of YYYY-MM-DD HH:MM.

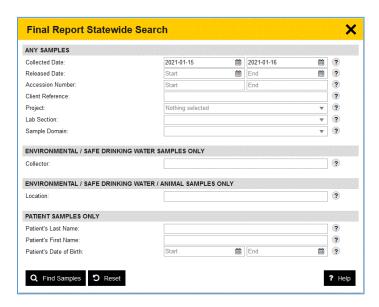


Figure 91 Searching by a Collected Date Range

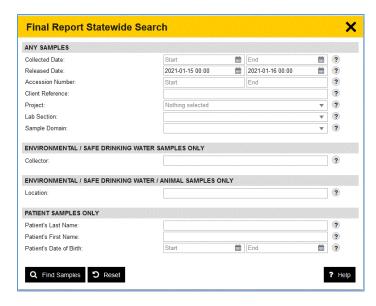


Figure 92 Searching by a Released Date Range

A search can be narrowed by entering information in multiple fields. For example, to find all of the samples for patient Jane Doe who was born on March 11, 2024, enter DOE in the **Patient's Last Name** field, JANE in the **Patient's First Name** field, and 2024-03-11 in the **Patient's Date of Birth** Start field. To search by a range of dates enter a Start date and an End date.

A search may also be limited to one or more projects, performing lab sections, or a sample domain. If these fields are left empty, all samples to which you are authorized will be displayed regardless of their performing lab section, sample domain, or whether they have an assigned project.

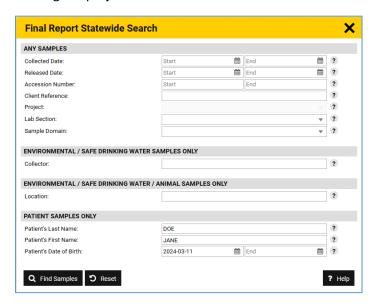


Figure 93 Searching by a Patient's Last Name, First Name, and Date of Birth

The system supports wild card searches in the following fields: **Client Reference**, **Patient's Last Name** and **Patient's First Name**. To use this search method, add an * at the beginning and/or end of the search term. Below are two examples:

- To see a list of samples for a patient whose last name starts with the letters "SCHM", enter SCHM* in the **Patient's Last Name** field. Matches would include SCHMIDT, SCHMITT, SCHMITT, etc.
- To see a list of samples for a patient whose first name ends with the letters "JO", enter *JO in the **Patient's First**Name field. Matches would include BETTY JO, BETTYJO, JO, etc.

Draft Version 2 2024 Michael B. Hayek 58

Click on the Tool Tip ? to the right of each field to view information about the use and format of that field.

Click the **Find Samples** button to display a list of samples that match the search criteria. The **Reset** button clears all of the search fields.

Viewing Final Reports

A list of samples that match the search criteria will be displayed on the next screen.

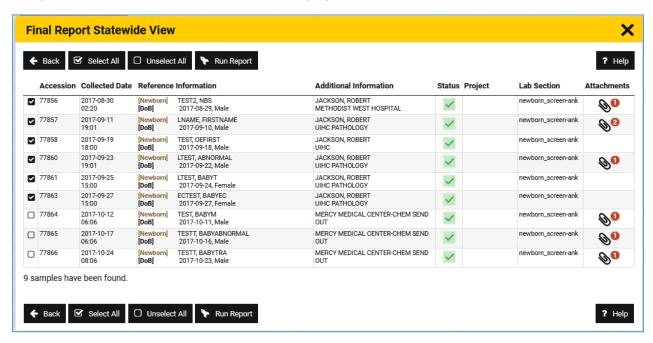


Figure 94 Final Report Statewide View

To view reports for all of the listed samples, click the **Select All** button, and then the **Run Report** button.

To view specific reports, check the boxes in front of their **Accession** numbers, and then click the **Run Report** button.

The PDF reports of the selected samples will pop up. Reports may be viewed, saved, or printed.

The following are descriptions of each column on this screen.

Accession: The lab number assigned to the sample by the laboratory.

Collected Date: The date (and time if submitted) that the sample was collected. All dates and times have the format of YYYY-MM-DD HH:MM.

Reference Information: This information can be helpful in identifying a sample. The newborn's name, date of birth (DoB), and gender are usually displayed for newborn screening samples.

Additional Information: This information can also be useful in identifying a sample. The ordering health care provider's name (if submitted) and "Report To" organization are displayed for newborn screening samples.

Status: The sample's status is shown here. "In Progress" samples have one or more tests that are not yet complete and at least one test that is finished. The finished test's results are currently available on the Final Report. "Completed" samples have finished testing, and all of their results are available on the Final Report. Exception: Newborn screening test results will only be displayed through the Final Report Statewide and the Spreadsheet View Statewide modules after all of the tests on the panel have been completed.

Project: The name of the project that has been assigned to the sample. A project can be used to group samples with a similar purpose.

Lab Section: The name(s) of the laboratory section(s) that performed the test(s) on the sample.

Attachments: The number of documents attached to each sample (if any) are shown in this column in a red circle. First, click on the paper clip icon to display the list of attachments. Next, click on the name of the attachment to display it. Attachments may include the test request form (begins with the prefix "TRF"), original and subsequent versions of final reports (begin with the prefix "FinalReport"), copies of email correspondence, send-out lab reports, and laboratory instrument output.

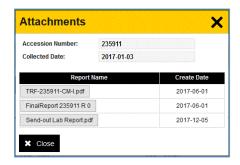


Figure 95 Sample Attachment List

Spreadsheet View Statewide Screen

The Spreadsheet View Statewide screen allows the user to search for and download data into a spreadsheet for a particular sample domain(s) for samples that were submitted by organizations anywhere in a state or for patients that reside in a specified state. For instance, the user may have permissions to search for and download the reportable data for any newborn screening samples submitted to the laboratory for patients that reside in a specified state.

Click on the **Spreadsheet View Statewide** button (or select it from the General Reports menu).

The first step is to search for the data to be displayed in the spreadsheet. The Spreadsheet View Statewide search screen works the same way as the Final Report Statewide search screen. See <u>Query Fields</u> in the **Final Report Statewide Screen** section for suggestions on how to conduct a search.

Use the **Open Query** button to navigate to a saved query (in XML format) to run, if desired. This feature is useful to generate a similar spreadsheet on a periodic basis without having to enter the search fields and select the data output fields.

After entering the search information, click the **Continue to Report Fields** button. The **Reset** button clears all of the search fields.

On the next screen select the fields to be displayed as columns on the spreadsheet. Individual fields can be selected or all of the fields in a group can be selected by clicking the **Select All** button.

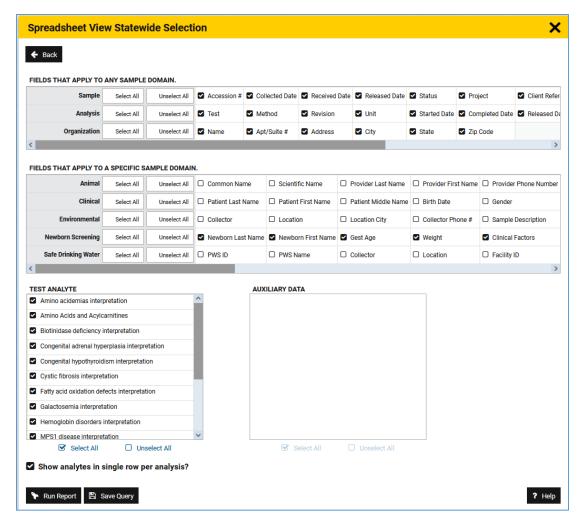


Figure 96 Selecting Fields to Output to a Spreadsheet for Newborn Screening Samples

This screen also shows all of the test analytes and auxiliary data that match the search criteria. Select at least one **Test Analyte** or **Auxiliary Data** field to run the report. Use the **Select All** button at the bottom to output all of the available information in a group.

The **Show analytes in single row per analysis?** option allows all of the test analyte values and auxiliary data for an analysis to be displayed as a single row on the spreadsheet.

Click the **Run Report** button to generate the spreadsheet containing the data that was selected. Spreadsheets can be viewed, saved, or printed.

<u>Exception</u>: Newborn screening test results will only be displayed through the Final Report Statewide and the Spreadsheet View Statewide modules after all of the tests on the panel have been completed.

Use the **Save Query** button to save a query (in XML format) to run again in the future. This feature is useful to generate a similar spreadsheet on a periodic basis without having to enter the search fields and select the data output fields.

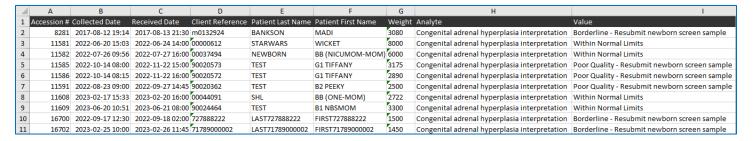


Figure 97 Spreadsheet View of Newborn Screening Samples

Disclaimer

Results from the **Spreadsheet View** represent analytical values as of the date they are generated. Future revisions may affect these results and official final results should be reviewed from the **Final Report** option to assure their accuracy.

Test Status Statewide Screen

The Test Status Statewide screen will display the status of each test that is being performed on the queried samples. The Lab Section, Collected Date, Received Date, Client Reference, and any QA Events will also be shown. The user will have access to view the status of any test of a particular sample domain(s) for samples that were submitted by organizations anywhere in a state or for patients that reside in a specified state. For instance, the user may have permissions to view the status of any newborn screening samples submitted to the laboratory for patients that reside in a specified state.

Click on the **Test Status Statewide** button (or select it from the General Reports menu).

The first step is to search for the desired samples. The Test Status Statewide search screen works the same way as the Final Report Statewide search screen. See <u>Query Fields</u> in the **Final Report Statewide Screen** section for suggestions on how to conduct a search.

After entering the search information, click the Find Samples button. The Reset button clears all of the search fields.

A list of samples matching the search criteria will be displayed. The real-time status of each test that is being performed is shown. Samples will not be displayed until they have been entered into and verified through the laboratory's information system.

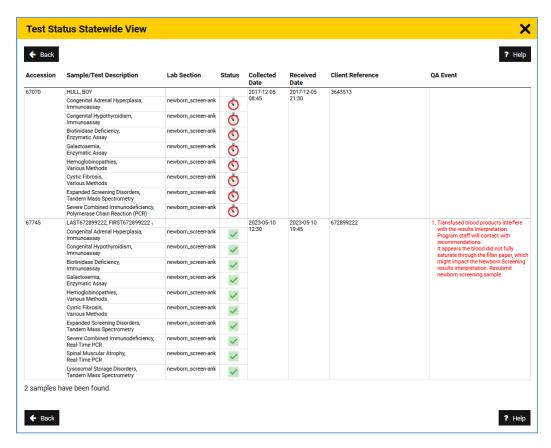


Figure 98 Test Status Statewide View

The following are descriptions of each column on this screen.

Accession: The lab number assigned to the sample by the laboratory.

Sample/Test Description: The Sample Description is displayed in the first row for each Accession number. The patient's name (in uppercase letters) is usually displayed for patient samples. The collector's name (in lowercase letters) is usually displayed for environmental and safe drinking water samples. The type of animal is displayed for animal samples (e.g., rabies testing). The Test Descriptions are displayed in the remaining rows for each Accession number. They consist of the "test name, method name". There may be a footnote at the end of a Sample or Test Description which is explained in the QA Event column. If a footnote is after the Sample Description, it applies to the entire sample. If a footnote is after a Test Description, it only applies to that test.

Lab Section: The name of the laboratory section that performed each test on the sample.

Status: The test's status is shown here. "In Progress" tests have not been finished. "Completed" tests have finished testing, and their results are available through the Final Report Statewide and the Spreadsheet View Statewide modules. Exception: Newborn screening test results will only be displayed through the Final Report Statewide and the Spreadsheet View Statewide modules after all of the tests on the panel have been completed.

Collected Date: The date (and time if submitted) that the sample was collected. All dates and times have the format of YYYY-MM-DD HH:MM.

Received Date: The date and time that the sample was received at the laboratory. All dates and times have the format of YYYY-MM-DD HH:MM.

Client Reference: An item of information that helps to identify a sample. It could be the organization's lab number, a patient ID/Chart ID/Medical Record Number, or another identifier for a sample.

QA Event: Any quality assurance issue that applies to the entire sample or an individual test is displayed in this column.

Newborn Reports

Newborn CollN Report

The Newborn Collaborative Improvement and Innovation Network (CoIIN) Report is designed to improve timeliness in newborn screening by displaying an organization's distribution of samples by the time between the birth of the newborn and the receipt of the sample at the newborn screening laboratory. This report also compares the organization's current performance to their performance during a reference period and the performance of all newborn screening organizations across the state. Click on the **Newborn Colin** button (or select it from the Newborn Reports menu).

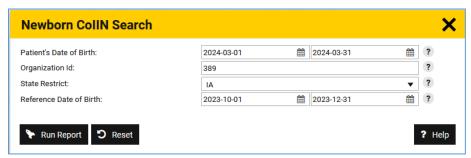


Figure 99 Newborn CollN Report Search Screen

The following are descriptions of each field on this screen.

Patient's Date of Birth: The patient's date of birth is used for the timeframe of the report. The screen defaults to searching for the newborns born over the past month. However, the date range can be changed to meet the user's needs. It is recommended to click in a date field and use the calendar when entering a date to eliminate any formatting errors. Clicking on the word "TODAY" at the bottom of the calendar will insert the current date. Dates can also be typed, if preferred. All dates have the format of YYYY-MM-DD.

Organization Id: The report can be limited to the newborn screening samples that were reported to one "Report To" organization. Enter the OpenELIS organization id of the desired organization. Leave this field empty to display the newborn screening samples from all organizations for a state.

State Restrict: The report must be limited to the newborn screening samples from one state. Select the desired state to limit the search.

Reference Date of Birth: These patient date of birth fields are used to create reference performance distributions for the specific organization and the state. These fields default to the beginning and ending dates of the prior quarter, but they can be changed by the user.

Click on the Tool Tip ? to the right of each field to view information about the use and format of that field.

Click the **Run Report** button to display a PDF of the report. The **Reset** button re-enters the default dates.

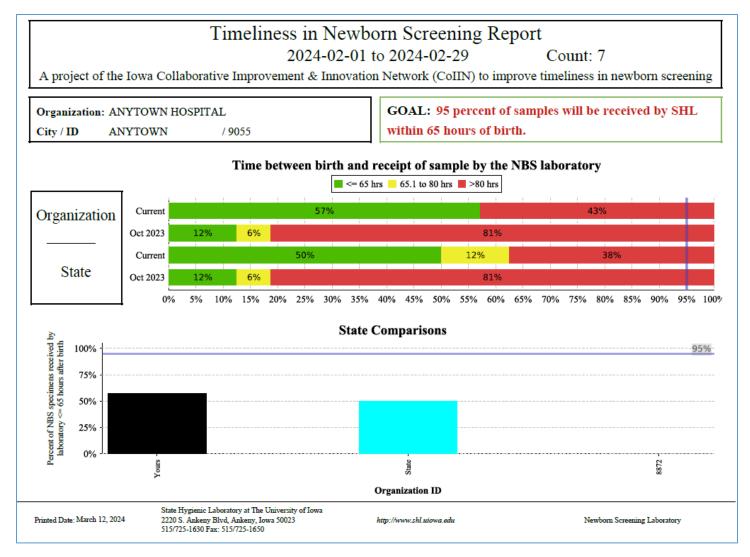


Figure 100 Newborn CollN Report

The following are descriptions of each section of this report.

Report Header

The description and the current report period of the report, and the count of released initial newborn screening samples submitted by the organization is displayed in this section.

Organization, City, ID

The name, city, and OpenELIS id of the "Report To" organization is displayed in this section. Results are reported to the "Report To" organization through mail, the OpenELIS Web Portal, and/or an electronic results interface.

Goal

The organizational and statewide goal of this CollN project is displayed here.

Time between birth and receipt of sample by the NBS laboratory

The distribution of the times between the births of the newborns and the receipt of the samples at the newborn screening laboratory is displayed as four horizontal bars on a graph. A blue line marks the project's goal (95%).

• The organization's percentage distribution of samples for the current report period is displayed in the first bar.

Draft Version 2 2024 Michael B. Hayek 65

- The organization's percentage distribution of samples for the reference report period is displayed in the second bar.
- The state's percentage distribution of samples for the current report period is displayed in the third bar.
- The state's percentage distribution of samples for the reference report period is displayed in the fourth bar.

Each bar graph is divided into three color-coded ranges. A range will not be displayed if there were not any samples in that range during the time period.

- <= 65 hrs. (green)</p>
- 65.1 to 80 hrs. (yellow)
- > 80 hrs. (red)

State Comparisons

The percentages of newborn screening samples received by the laboratory <= 65 hours after birth are displayed as a series of color-coded vertical bars on a graph. A blue line marks the project's goal (95%). At least 10 initial newborn screening samples must be released during the report period to be displayed as a bar in this graph.

- The specified organization's bar is labeled "Yours" (black).
- The state's bar is labeled "State" (aqua).
- The bars of other organizations in the state are labeled with their OpenELIS organization ID (gray).

Report Footer

The date that the report was generated, and the name, address, and contact information of the newborn screening laboratory is displayed in this section.

Newborn Birth Match Report

The Newborn Birth Match Report displays the details of newborn screening samples in order to match them to the newborns' birth records. Click on the **Newborn Birth Match** button (or select it from the Newborn Reports menu).

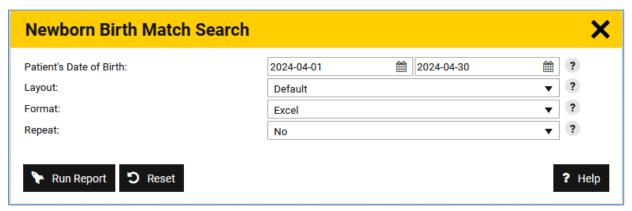


Figure 101 Newborn Birth Match Report Search Screen

The following are descriptions of each field on this screen.

Patient's Date of Birth: The patient's date of birth is used for the timeframe of the report. It is recommended to click in a date field and use the calendar when entering a date to eliminate any formatting errors. Clicking on the word "TODAY" at the bottom of the calendar will insert the current date. Dates can also be typed, if preferred. All dates have the format of YYYY-MM-DD.

Layout: It is required to select the layout of the report: Default or Alaska.

Format: It is required to select the format of the report: Excel or CSV. CSV files will normally open in Excel by default.

Repeat: Select whether repeat newborn screens should be included in the report ("Yes") or not ("No"). If this field is left empty, both initial and repeat screens will be included in the report.

Click on the Tool Tip ? to the right of each field to view information about the use and format of that field.

Click the **Run Report** button to generate the report. The **Reset** button clears all of the search fields.

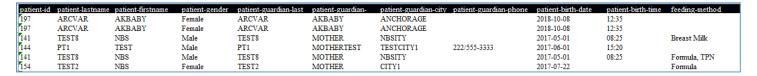


Figure 102 Newborn Birth Match Report

Samples that match the search parameters are outputted as rows on the spreadsheet. The following are descriptions of each column on this report.

patient-id

The unique id of the patient as automatically assigned by OpenELIS.

patient-lastname

The last name of the patient as provided to the laboratory.

patient-firstname

The first name of the patient as provided to the laboratory.

patient-gender

The assigned sex at birth of the patient as provided to the laboratory. Options are Female, Male, and Unknown.

patient-guardian-last

The last name of the patient's guardian as provided to the laboratory.

patient-guardian-first

The first name of the patient's guardian as provided to the laboratory.

patient-guardian-address1

The residing address of the patient's guardian as provided to the laboratory. This column is only available on the "Alaska" layout of the report.

patient-guardian-city

The residing city of the patient's guardian as provided to the laboratory.

patient-guardian-zip

The residing zip code of the patient's guardian as provided to the laboratory. This column is only available on the "Alaska" layout of the report.

patient-guardian-phone

The phone number of the patient's guardian as provided to the laboratory.

patient-birth-date

The birth date of the patient as provided to the laboratory is displayed in the format of YYYY-MM-DD.

patient-birth-time

The birth time of the patient as provided to the laboratory is displayed in the format of HH:MM.

feeding-method

The feeding method of the newborn is displayed here, if provided. Options include Breast Milk, Formula, TPN, and their various combinations, and None of the above.

received-date

The date and time that the sample was received at the performing laboratory is displayed in the format of YYYY-MM-DD HH:MM.

accession-no

The number (id) assigned to the sample by the performing laboratory.

client-reference

An identifier that was provided for the sample or patient by the submitting organization. It could be the organization's sample number, a patient ID, Chart ID, or Medical Record Number (MRN).

organization-id

The OpenELIS id of the "Report To" organization is displayed in this column. Results are reported to the "Report To" organization through mail, the OpenELIS Web Portal, and/or an electronic results interface.

organization-name

The name of the "Report To" organization is displayed in this column.

collected-datetime

The date and time that the sample was collected is displayed in the format of YYYY-MM-DD HH:MM. If either the Collected Date or Collected Time is missing, the cell will be empty.

collection-valid

This column denotes whether the sample collection was valid. Collections are valid when the <u>Collection Age</u> of the newborn is \geq 24:00 hours. Values include Yes, No, and Unknown. An "Unknown" value is displayed when the <u>Collection Age</u> cannot be calculated or estimated by the software and, thus, is empty.

repeat

This column denotes whether the sample is for a repeat screen. Values are Y and N.

rejected-ga

The name of any reject (poor quality) quality assurance event assigned to the sample is displayed here.

weight

The weight of the newborn in grams when the samples was collected is shown here, if provided.

transfusion-interference

This column displays whether a transfusion is potentially interfering with the newborn screening test interpretations. Values include Yes, No, and Unknown. These conditions are defined as:

Transfusion Interference = Yes is when "Transfused" is marked "Yes" in the internal OpenELIS system and there is a "Transfused Date" present in the internal OpenELIS system that is < 56 days before the sample Collected Date.

Transfusion Interference = Unknown is when "Transfused" is marked "Yes" in the internal OpenELIS system but no "Transfused Date" is provided or when "Transfused" is marked "No" in the internal OpenELIS system, but a "Transfused Date" is provided that is < 56 days before the sample Collected Date or when "Transfused" is marked "Unknown" in the internal OpenELIS system regardless of whether a "Transfused Date" is provided.

Transfusion Interference = No is when "Transfused" is marked "No" in the internal OpenELIS system and there is no "Transfused Date" present in the internal OpenELIS system or when "Transfused" is marked "Yes" or "No" in the internal OpenELIS system, but a "Transfused Date" is provided that is >= 56 days before the sample Collected Date.

sample-released-date

The date and time that the results of the entire sample were released is displayed in the format of YYYY-MM-DD HH:MM. This corresponds to the date and time that the last test on the sample was released.

container-reference

This column can be used to display the serial number of a newborn screening dried blood spot collection card.

cpt1a-interp

The CPT1a interpretation of the CPT1A Arctic Variant (c.1436C>T), Real-Time PCR test is displayed in this column. The interpretations are Negative, Indeterminate - Arctic Variant, Homozygous-CPT1A Arctic Variant, and Inconclusive - Resubmit newborn screen sample. This column is only available on the "Alaska" layout of the report.

arctic-variant-genotype

The Arctic Variant Genotype of the CPT1A Arctic Variant (c.1436C>T), Real-Time PCR test is displayed in this column. The values are Homozygous G/G, Heterozygous G/A, Homozygous A/A, and Undetermined. This column is only available on the "Alaska" layout of the report.

Newborn Feeding Report

The Newborn Feeding Report calculates and displays the counts of the various feeding methods of newborns per organization, county, and the total for the report timeframe. Click on the **Newborn Feeding** button (or select it from the Newborn Reports menu).

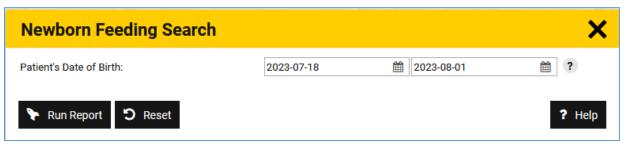


Figure 103 Newborn Feeding Report Search Screen

The following are descriptions of each field on this screen.

The **Patient's Date of Birth** is used for the timeframe of the report. The screen defaults to searching for the newborns born over the past 2 weeks. However, the date range can be changed to meet the user's needs. It is recommended to click in a date field and use the calendar when entering a date to eliminate any formatting errors. Clicking on the word "TODAY" at the bottom of the calendar will insert the current date. Dates can also be typed, if preferred. All dates have the format of YYYY-MM-DD.

Click on the Tool Tip ? to the right of each field to view information about the use and format of that field.

Click the **Run Report** button to display a PDF of the report. The **Reset** button re-enters the default dates.

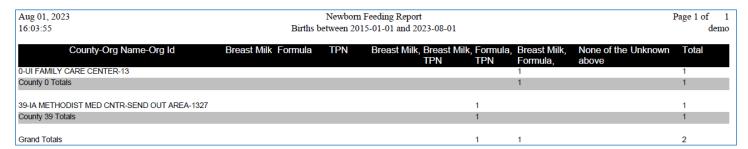


Figure 104 Newborn Feeding Report

The following are descriptions of each section/column on this report.

Report Header

The date and time that the report was generated is displayed in the upper left corner. The name of the report and the date range is displayed in the top middle section. The page number and username of the person who generated the report is displayed in the upper right corner.

County-Org Name-Org Id

The county code of the "Report To" organization is displayed first. This is followed by the name and OpenELIS id of the "Report To" organization. Results are reported to the "Report To" organization through mail, the OpenELIS Web Portal, and/or an electronic results interface. "Report To" organizations are grouped by county.

Feeding Methods

The various <u>feeding methods</u> and their combinations are displayed as separate columns on the report. The number of newborns from that organization that used each feeding method or combination are displayed in that organization's row. If a feeding method was not provided for a newborn, they are assigned to the "Unknown" column.

"Report To" Organization Total

The total number of newborns for a "Report To" organization is displayed at the end of the organization's row.

County Totals

The county totals for the various feeding methods and their combinations are displayed in the gray rows. The total number of newborns for a county is displayed at the end of the county's row.

Grand Totals

The grand totals for the various feeding methods and their combinations are displayed at the bottom of the report. The total number of newborns for the report is displayed at the end of the Grand Totals row.

Newborn Samples QA Statewide Report

The Newborn Samples QA Statewide Report displays the patients having quality assurance (QA) issues with their newborn screening samples. The samples must be in released status to be displayed in the report. These samples could be submitted by organizations anywhere in a state or for patients that reside in a specified state. The totals of each category of QA issues and the combined total are displayed for each "Report To" organization. Results are reported to the "Report To" organization through mail, the OpenELIS Web Portal, and/or an electronic results interface. Click on the **Newborn Samples QA Statewide** button (or select it from the Newborn Reports menu).

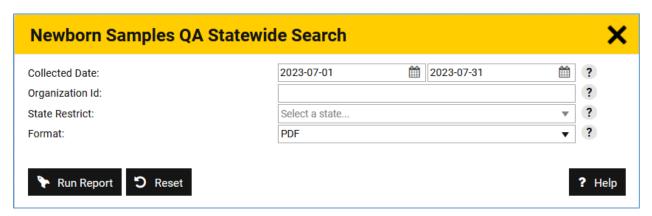


Figure 105 Newborn Samples QA Statewide Report Search Screen

The following are descriptions of each field on this screen.

Collected Date: The date that the sample was collected is used for the timeframe of the report. It is recommended to click in a date field and use the calendar when entering a date to eliminate any formatting errors. Clicking on the word "TODAY" at the bottom of the calendar will insert the current date. Dates can also be typed, if preferred. All dates have the format of YYYY-MM-DD.

Organization Id: The report can be limited to the newborn screening samples with QA issues that were reported to one "Report To" organization. Enter the OpenELIS organization id of the desired organization. Leave this field empty to display the newborn screening samples with QA issues from all organizations for which you have permissions.

State Restrict: The report can be limited to the newborn screening samples with QA issues from one state. Select the desired state to limit the search. Leave this field empty to display the newborn screening samples with QA issues from all states for which you have permissions.

Format: It is required to select the format of the report: PDF or CSV. CSV files will normally open in Excel by default.

Click on the Tool Tip ? to the right of each field to view information about the use and format of that field.

Click the **Run Report** button to generate the report. The **Reset** button clears all of the search fields.

7768 - MARY GREELEY MEDICAL CENTER LAB, AMES, IA

Patient Name	Client Reference	Poor Quality	Early Collection	Unknown Transfusion	
LAST672899222, FIRST672899222	672899222	Did not saturate			
Total Samples 1			1	0	0

Note: Early collection may be appropriate in some instances such as if infant will be transferred or discharged prior to 24 hours. Also if an infant will receive a transfusion before the infant is 24 hours old then an early collection prior to transfusion is appropriate and recommended.

7769 - MERCY MEDICAL CENTER-CHEM SEND OUT, DES MOINES, IA

Patient Name	Client Reference	Poor Quality	Early Collection	Unknown Transfusion
TESTT, BABYTRA	002451232			X
TESTT, BABYEC	00004321		X	
TESTMERCY, TUNKNOWN	87654324			X
TESTMERCY, EARLYC	87654326		X	
TESTMERCY, EARLYCU	87654327		X	
Total Samples 5			0	3 2

Note: Early collection may be appropriate in some instances such as if infant will be transferred or discharged prior to 24 hours. Also if an infant will receive a transfusion before the infant is 24 hours old then an early collection prior to transfusion is appropriate and recommended.

Figure 106 Newborn Samples Quality Assurance Report (PDF version)

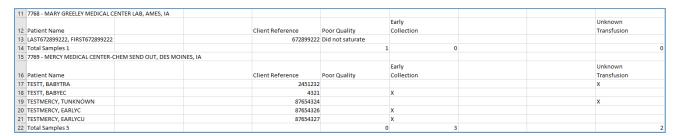


Figure 107 Newborn Samples Quality Assurance Report (CSV version)

The following are descriptions of each section/column on this report.

Report Header

The date and time that the report was generated is displayed in the upper left corner. The name of the report and the date range is displayed in the top middle section. The page number and username of the person who generated the report is displayed in the upper right corner.

Organization Id-Organization Name, City, State

The OpenELIS id, name, city, and state of the "Report To" organization for the newborn screening samples with QA issues is displayed at the top of the section. Results are reported to the "Report To" organization through mail, the OpenELIS Web Portal, and/or an electronic results interface.

Patient Name

The last name, first name of the newborn is displayed in this column.

Client Reference

An item of information that helps to identify a sample. It could be the organization's lab number, a patient ID/Chart ID/Medical Record Number, or another identifier for a sample.

Poor Quality

A poor quality issue with the sample is displayed here. These include Apply both sides, Clotted, Did not saturate, Expired Device, FP contaminated, FP damaged, Layered, No blood applied, Quant not suffic, Sample age, Serum separation.

Early Collection

If the newborn screening sample was an "Early Collection" (the sample was collected prior to 24 hours after the newborn's birth), an "X" will be displayed in this column.

Early Collection Unknown

If the newborn screening sample was an "Early Collection Unknown" (it cannot be determined if the sample was collected early), an "X" will be displayed in this column.

Unknown Transfusion

If the newborn screening sample was an "Unknown Transfusion" (it cannot be determined if the newborn was transfused with any blood products before the sample was collected), an "X" will be displayed in this column.

Total Samples

The total number of samples with QA issues for the organization is displayed in the bottom row of the organization's section. The total number of samples for each category of QA issues is also displayed in this row.

Newborn State Summary Report

The Newborn State Summary Report provides counts of released samples of poor quality, with missing information, and with abnormal results, and also calculates average turnaround times for each "Report To" organization listed on the report. The report totals are also calculated for each of these categories. Click on the **Newborn State Summary** button (or select it from the Newborn Reports menu).



Figure 108 Newborn State Summary Search Screen

The following are descriptions of each field on this screen.

Patient's Date of Birth: The patient's date of birth is used for the timeframe of the report. It is recommended to click in a date field and use the calendar when entering a date to eliminate any formatting errors. Clicking on the word "TODAY" at the bottom of the calendar will insert the current date. Dates can also be typed, if preferred. All dates have the format of YYYY-MM-DD.

State Restrict: The report must be limited to data from one state. Select the desired state to limit the search.

Click on the Tool Tip ? to the right of each field to view information about the use and format of that field.

Click the **Run Report** button to generate the spreadsheet. The **Reset** button clears all of the search fields.

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11:04:49)	From	2015-01-01	to 2023-0	8-04				demo													
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8484	MERCY CAMPUS CLINIC		1	0 1	ı 💆	0 💆	0	0	0	0 💆	0 💆	0 💆	0 () 💆 () () "	0.0	0	0'	•	0 💆	0
8543	METHODIST WEST HOSPITAL	•	3	3 () *	0	0	0	0	0	0 💆	0 💆	0 () () () "	0.0	1	1	•	0 💆	0
8871	UIHC		2	2 () •	0	0	0	0	0	0 💆	0 💆	0 () () () 💆	0.0	0	0	•	0	0
8872	UIHC PATHOLOGY	•	28 ⁷ 2	17 1	7	0 💆	0	0	0	0 💆	0 💆	0 💆	0 () 💆 () () "	0.0	1	4	•	0 💆	2
9055	ANYTOWN HOSPITAL		5	5 () •	0	0	1	0	0	0 💆	0 💆	0 () () () "	1 20.0	0	0		0 💆	1
10127	AVERA ST. LUKES HOSPITAL		3	2	ı 💆	0	0	0	0	0 💆	0 💆	1	0 () 💆 () () "	1 50.0	0	0'	•	0 💆	0
10292	TRINITY HEALTH MEDICAL	•	13	7	5	0	0	0	0	0 💆	0 💆	0 💆	1 () () () "	1 14.3	0	2		0 💆	0
10318	ANYTOWN HOSPITAL		1	1 () •	0	0	0	0	0	0	0 💆	0 () 💆 () () "	0.0	0	0		0 💆	0
10319	ANYTOWN HOSPITAL		1	1 () *	0	0	0	0	0 💆	0 💆	0 💆	0 () 💆 () () "	0.0	0	0	•	o "	0
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Figure 109 Newborn State Summary Report

The following are descriptions of each section/column on this report.

Report Header

The date and time that the report was generated is displayed in the upper left corner. The name of the report and the date range is displayed in the top middle section. The page number and username of the person who generated the report is displayed in the upper right corner.

Organization ID

The OpenELIS id of the "Report To" organization is displayed in this column. Results are reported to the "Report To" organization through mail, the OpenELIS Web Portal, and/or an electronic results interface.

Organization name

The name of the "Report To" organization is displayed in this column.

Total samples

The total number of samples (both initial and repeat) reported to the organization is displayed here.

Initial samples

The number of initial samples reported to the organization is displayed here.

Repeat samples

The number of repeat samples reported to the organization is displayed here.

The next 11 columns display the number of each type of reject (poor quality) samples reported to the organization. A newborn screening sample should have been resubmitted for testing.

Sample age

The sample was received by the laboratory at least 14 days after the sample was collected, which might impact the Newborn Screening results interpretation.

Apply both sides

It appears the blood was applied to both sides of the filter paper, which might impact the Newborn Screening results interpretation.

FP contaminated

It appears the blood on the filter paper is contaminated, which might impact the Newborn Screening results interpretation.

Did not saturate

It appears the blood did not fully saturate through the filter paper, which might impact the Newborn Screening results interpretation.

Layered

It appears multiple drops of blood overlap or were layered on the filter paper, which might impact the Newborn Screening results interpretation.

Clotted

The blood on the filter paper is clotted, which might impact the Newborn Screening results interpretation.

Quant not suffic

An insufficient quantity of blood was applied to the filter paper, so Newborn Screening analysis cannot be completed.

Serum separation

The red blood cells and serum appear separated on the filter paper, which might impact the Newborn Screening results interpretation.

FP damaged

The filter paper collection device is damaged, which might impact the Newborn Screening results interpretation.

No blood applied

The Newborn Screen could not be completed because no blood was applied to the filter paper.

Expired Device

The device used to collect this sample was expired. Samples collected using expired devices might impact the Newborn Screening results interpretation.

Reject total

The total number of reject (poor quality) samples reported to the organization is displayed here.

Reject rate

The percentage of initial samples reported to the organization that were rejected is displayed here. Reject rate = Reject total/Initial samples x 100

Early Collection

The number of samples that were collected prior to 24 hours after the newborn's birth by the organization is displayed here.

Transfused

The number of samples reported to the organization with a transfused status for the newborn is displayed here.

Transfused unknown

The number of samples reported to the organization with an unknown transfusion status for the newborn is displayed here. In this situation it cannot be determined if the newborn was transfused with any blood products before the sample was collected.

Weight unknown

The number of samples reported to the organization where the current weight of the newborn when the sample was collected was unknown is displayed here.

Birth - Collection

The average turnaround time from the birth of a newborn to the collection of their newborn screening sample for the organization is displayed in this column in days.

Collection - Received

The average turnaround time from the collection of the newborn screening sample to its receipt in the laboratory for the organization is displayed in this column in days.

Received - Released

The average turnaround time from the receipt in the laboratory of the newborn screening sample to the release of its results for the organization is displayed in this column in days.

Birth - Released

The average turnaround time from the birth of a newborn to the release of their newborn screening results for the organization is displayed in this column in days.

TAT count

The number of newborn screening samples that were used to calculate the 4 turnaround times (described above) for the organization. Samples with revisions > 0 are excluded from the TAT calculations since they will have a later released date that will skew the average Received - Released and Birth - Released turnaround times.

BT PP

The number of samples reported to the organization with a presumptive positive interpretation for Biotinidase Deficiency.

CAH PP

The number of samples reported to the organization with a presumptive positive interpretation for Congenital Adrenal Hyperplasia.

CAH BORD

The number of samples reported to the organization with a borderline interpretation for Congenital Adrenal Hyperplasia.

CAH total

The number of samples reported to the organization with either a presumptive positive or a borderline interpretation for Congenital Adrenal Hyperplasia.

CF PP

The number of samples reported to the organization with a presumptive positive interpretation for Cystic Fibrosis.

CF BORD

The number of samples reported to the organization with a Possible Cystic Fibrosis interpretation.

CF total

The number of samples reported to the organization with either a presumptive positive or a possible interpretation for Cystic Fibrosis.

Galt PP

The number of samples reported to the organization with a presumptive positive interpretation for Galactosemia.

Galt BORD

The number of samples reported to the organization with a borderline interpretation for Galactosemia.

Galt total

The number of samples reported to the organization with either a presumptive positive or a borderline interpretation for Galactosemia.

HB Disease

The number of samples reported to the organization with a disease interpretation for Hemoglobinopathies.

MS/MS AA

The number of samples reported to the organization with an abnormal analyte on the Expanded Screening Disorders by Tandem Mass Spectrometry test.

TSH PP

The number of samples reported to the organization with a presumptive positive interpretation for Congenital Hypothyroidism.

TSH BORD

The number of samples reported to the organization with a borderline interpretation for Congenital Hypothyroidism.

TSH total

The number of samples reported to the organization with either a presumptive positive or a borderline interpretation for Congenital Hypothyroidism.

Report Total Columns

The rest of the columns (beginning with the prefix "T_") display the totals of every category for all organizations that are listed on the report. These totals are displayed in every cell of the column. The only "T_" columns that do not display totals are the T_Birth – Collection, T_Collection – Received, T_Received – Released, T_Birth – Released, and T_Reject rate that display the average turnaround times and the average Reject Rate for all organizations that are listed on the report.

Newborn Turnaround Statewide Report

The Newborn Turnaround Statewide Report displays the turnaround times for individual newborn screening samples and the average turnaround times for a "Report To" organization over a selected time period. The samples must be in Draft Version 2 2024

Michael B. Hayek

77

released status to be displayed in the report. These samples could be submitted by organizations anywhere in a state or for patients that reside in a specified state. Results are reported to the "Report To" organization through mail, the OpenELIS Web Portal, and/or an electronic results interface. Click on the **Newborn Turnaround Statewide** button (or select it from the Newborn Reports menu).

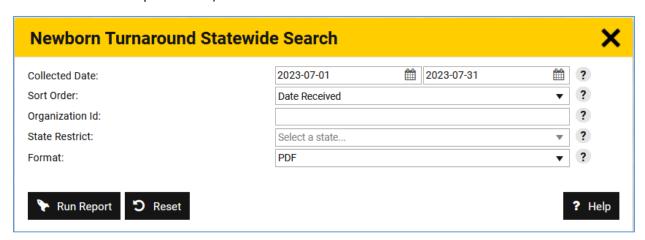


Figure 110 Newborn Turnaround Statewide Report Search Screen

The following are descriptions of each field on this screen.

Collected Date: The date that the sample was collected is used for the timeframe of the report. It is recommended to click in a date field and use the calendar when entering a date to eliminate any formatting errors. Clicking on the word "TODAY" at the bottom of the calendar will insert the current date. Dates can also be typed, if preferred. All dates have the format of YYYY-MM-DD.

Sort Order: A sort order must be selected for the report. Samples within a "Report To" organization can be sorted in ascending order by Date Received or by Birth to Collection, Collection to Received, Received to Released, Birth to Received, or Birth to Released turnaround times.

Organization Id: The report can be limited to the newborn screening samples that were reported to one "Report To" organization. Enter the OpenELIS organization id of the desired organization. Leave this field empty to display the newborn screening samples from all organizations for which you have permissions.

State Restrict: The report can be limited to the newborn screening samples from one state. Select the desired state to limit the search. Leave this field empty to display the newborn screening samples from all states for which you have permissions.

Format: It is required to select the format of the report: PDF or CSV. CSV files will normally open in Excel by default.

Click on the Tool Tip ? to the right of each field to view information about the use and format of that field.

Click the Run Report button to generate the report. The Reset button clears all of the search fields.

			Birth to	Collection E	Birth to	Receive to	Birth to
Patient Name	Client Reference	Repeat	Collection 1	to Receive F	Receive	Release	Release
BROWN, CHARLIE	569834527282		25	12	30	67	4 d 9 h
Total Samples 1	Average Turnaround Time (# of samples for averages)		25(1)	12 (1)	30 (1)	67 (1)	4 d 9 h (1)

Note: Repeat samples, samples with dates missing and samples collected greater than 5 days after birth are not used for determining averages. Times are in hours except for "Birth to Release" which is in days and hours.

10127 - AVERA ST. LUKES HOSPITAL, ABERDEEN, SD

			Birth to	Collection 1	Birth to	Receive to	Birth to
Patient Name	Client Reference	Repeat	Collection	to Receive	Receive	Release	Release
LAST3009856, FIRST3009856	3009856		24	24	40	42	3 d 19 h
LAST3019877, FIRST3019877	3019877		25	27	44	43	3 d 23 h
LAST3019877, FIRST3019877	3019877	X	47	29	68	19	3 d 23 h
Total Samples 3	Average Turnaround Time (# of samples for averages)		24(2)	25 (2)	42 (2	42 (2)	3 d 21 h (2)

Note: Repeat samples, samples with dates missing and samples collected greater than 5 days after birth are not used for determining averages. Times are in hours except for "Birth to Release" which is in days and hours.

Figure 111 Newborn Turnaround Report (PDF version)

	A	В	С	D	E	F	G	Н	I
	10318 - ANYTOWN								
1	HOSPITAL, ANYTOWN, SD								
2	Patient Name		Client Reference	Repeat	Birth to Collection	Collection to Receive	Birth to Receive	Receive to Release	Birth to Release
3	BROWN, CHARLIE		569834527282		25	12	30	67	4 d 9 h
		Average Turnaround Time (# of samples for							
4	Total Samples 1	averages)			25(1)	12 (1)	30 (1)	67 (1)	4 d 9 h (1)
	10127 - AVERA ST. LUKES								
5	HOSPITAL, ABERDEEN, SD								
6	Patient Name		Client Reference	Repeat	Birth to Collection	Collection to Receive	Birth to Receive	Receive to Release	Birth to Release
7	LAST3009856, FIRST3009856		3009856		24	24	40	42	3 d 19 h
8	LAST3019877, FIRST3019877		3019877		25	27	44	43	3 d 23 h
9	LAST3019877, FIRST3019877		3019877	X	47	29	68	19	3 d 23 h
		Average Turnaround Time (# of samples for							
10	Total Samples 3	averages)			24(2)	25 (2)	42 (2)	42 (2)	3 d 21 h (2)

Figure 112 Newborn Turnaround Report (CSV version)

The following are descriptions of each section/column on this report.

Report Header

The date and time that the report was generated is displayed in the upper left corner. The name of the report and the date range is displayed in the top middle section. The page number and username of the person who generated the report is displayed in the upper right corner.

Organization Id-Organization Name, City, State

The OpenELIS id, name, city, and state of the "Report To" organization for the newborn screening samples is displayed at the top of the section. Results are reported to the "Report To" organization through mail, the OpenELIS Web Portal, and/or an electronic results interface.

Patient Name

The last name, first name of the newborn is displayed in this column.

Draft Version 2 2024 Michael B. Hayek 79

Client Reference

An item of information that helps to identify a sample. It could be the organization's lab number, a patient ID/Chart ID/Medical Record Number, or another identifier for a sample.

Repeat

A repeat sample for the patient will have an "X" displayed in this column.

Birth to Collection

The turnaround time from the birth of the newborn to the collection of their newborn screening sample is displayed in this column in hours.

Collection to Receive

The turnaround time from the collection of the newborn screening sample to its receipt in the laboratory is displayed in this column in hours.

Birth To Receive

The turnaround time from the birth of the newborn to the receipt of their newborn screening sample in the laboratory is displayed in this column in hours.

Receive to Release

The turnaround time from the receipt in the laboratory of the newborn screening sample to the release of its results is displayed in this column in hours.

Birth to Release

The average turnaround time from the birth of a newborn to the release of their newborn screening results is displayed in this column in days and hours.

Total Samples

The total number of samples for the organization is displayed in the bottom row of the organization's section.

Average Turnaround Time (# of samples for averages)

The averages of each turnaround time are displayed here along with the number of samples that were used to calculate the averages.

Repeat samples, samples with dates missing, and samples collected greater than 5 days after birth are not used for determining averages.