Registered Lab/Manufacturer

User Guide

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HGNC: HUGO Gene Nomenclature Committee at the European Bioinformatics Institute http://www.genenames.org/

Contents

CHAPTER 1 OVERVIEW

WELCOME TO DEX™ DIAGNOSTICS EXCHANGE

This online help provides a step-by-step reference guide for using DEX to:

- **Browse** an extensive catalog of molecular, genetic, and other esoteric tests that are only performed at certain labs. (Chapter 3)
- **Adding** a lab test. (Chapter 4)
- **Sharing** with a Client Lab (Chapter 6)

Review the following sections to work with DEX:

- About Browsing the Catalog
- Adding a Lab Test

CHAPTER 2 USING THE MESSAGE CENTER

MESSAGE CENTER OVERVIEW

After logging in to DEX™ Diagnostics Exchange, a window automatically displays with targeted or timely messages about a production release. Messages are presented as QuickNotes and may include the following release information: updates, enhancements, bug fixes, and delays.

See the following sections for performing tasks with the Message Center:

- Using the Message Center Window
- Managing the Messages Queue
- Archiving Messages
- Restoring Messages

USING THE MESSAGE CENTER WINDOW

After logging into DEX™ Diagnostics Exchange, a message appears on the Message Center window if there are new or unread messages since the last login.

The red circle with the number in it, next to the Message Center menu option, refers to the number of messages that are unread.

To dismiss a message:

- Click Dismiss to close the Message Center window. The message remains unread in bold in the Messages queue. Open this message later from the Messages queue by accessing Message Center from the DEX menu.

To read the message:

- Click Read More to display a full message in a new window.

  The message is marked as read in the Messages queue, and the Message Center window closes.

For more than one message:

- Click Read More.

  DEX opens the Messages queue for viewing a list of unread messages in bold. The most recently sent message appears first.

When leaving DEX without clicking Dismiss or Read More:

- Unread messages automatically appear on the Message Center window for the next login.

Select Message Center on the DEX menu at any time to read messages on the Messages queue. Click the message title to open the message.

If there are no new or unread messages since the last login:

- The Message Center window does not display after login.

MANAGING THE MESSAGES QUEUE

After reading and closing a message received from the Message Center window, the message moves to the Messages queue. Open this queue at any time by selecting Message Center from the menu options. DEX™ Diagnostics Exchange defaults to the Messages tab that contains the queue.

The sort order displays the most recent message first (by default), but can be changed to display by date or subject.

Messages that appear in bold have not yet been read. The bold text disappears after reading the message. Open and read messages at any time. An Items Per Page indicator appears at the bottom of every page for scrolling through the pages of the archived message list.

To archive a message to the Archive queue, see Archiving Messages.

ARCHIVING MESSAGES

Archive a message from the Messages queue by selecting Archive to the left of the message. To select all messages, click Archive All above the list.

After confirming, a red alert appears on the Message queue indicating that the message has been archived and the message moves to the Archive queue.

The sort order displays the most recent message first (by default), but can be changed to display by date or subject. Messages cannot be deleted. Open and read messages at any time. An Items Per Page indicator appears at the bottom of every page for scrolling through the pages of the archived message list.

To restore a message back to the Messages queue, see Restoring Messages.

RESTORING MESSAGES

Select a message from the Archive queue, and then click Restore next to that message. To select all messages, click Restore All above the list.

After selecting Restore or Restore All and confirming that decision, the message or messages return to the Messages queue.

Open and read the message at any time. An Items Per Page indicator appears at the bottom of every page for scrolling through the pages of the archived message list.

To archive a message, see Archiving Messages.

CHAPTER 3 BROWSING THE CATALOG

ABOUT BROWSING THE CATALOG

A central part of DEX™ Diagnostics Exchange is the test catalog. This catalog comprises a broad array of molecular, genetic, and other esoteric tests and provides information about which labs perform them. For more information on how to use the test catalog, review the following topics:

- Browsing by Lab Test
- Browsing by Lab
- Browsing by DEX Z-Code™

There are several ways to search the catalog for returned results. For more information, see Searching for Content in the Catalog.

At the bottom of the Welcome screen are links to the privacy notice and how to contact DEX.

BROWSING THE LAB TEST CATALOG

After selecting the Lab Tests button, a window with a list of tests appears.

Tests appear with the test title, internal code from the performing lab, and the name of the performing lab or manufacturer. Select All to display all lab test titles in the catalog. Select the lab test title link to access lab test detail. For more information, see Lab Test Detail.

The Z-Code is only displayed if you are the performing lab for the test OR you have an approved sharing request with the performing lab. More on sharing can be found here My Organization: Sharing Lab Information

Lab Test Detail

When clicking on the lab test title link, the Lab Test Detail window appears.

The following detail appears about the selected lab test based on permissions, participation and sharing:

- **Name** — The name of the lab test.
- **Description** — The usage statement for the associated test or assay, including indications for ordering, limitations, etc. Acceptable format: free text entry. Rich text formatting is available for use. This information will be exposed for public view.
- **Lab/Mfr Test ID** —An identification number assigned to the lab test by the lab.
- **Lab/Manufacturer** — The lab or manufacturer submitting the test for coverage determination.
- **Methodology** — Method or procedure used to produce a test result.

- **FDA 510 (k)/PMA —** An indication of whether the test has been FDA cleared or approved.
- **FDA Document # —** The related FDA document number. If the value in the FDA field is Yes, then the lab is required to enter a number, otherwise the test cannot be saved. Also, indicates whether a lab has made any changes to a test after the FDA has approved it.
- **Coverage Tab** —Some tests may list coverage for the Palmetto GBA MolDX program.
- **Handling Tab —** a tab that contains specific instructions about how the specimen(s) needs to be handled.
- **Specimen Info Tab —** A tab that contains specimen information associated with the test.
- **Patient Instructions Tab —** A tab that contains patient instructions associated with the test.

BROWSING THE LABS AND MANUFACTURERS CATALOG

After selecting the Labs & Manufacturers button, a window with a list of labs and manufacturers appears.

Labs & Manufacturers display alphabetically by lab/manufacturer name in the Title column. Click All to display all labs/manufacturers in the catalog. Select the lab title link to access lab detail. For more information, see Lab Detail.

Use this Catalog to request Sharing with your reference lab:

- Search for the reference lab
- Click on the lab name or click the '+' sign to expand a parent organization's individual facilities to find the facility you send the specimen for testing.
- Select Request Sharing
- Once your reference lab approves your request, you can find their Z-Code in their test menu.

Lab Detail

When clicking on the link for the performing lab or manufacturer, either from the Lab Test or Lab browse windows, the Lab Detail window appears.

The following detail appears about the selected lab:

- **Name —** The name and/or logo of the performing lab.
- **Laboratory Type —** The type of laboratory, such as an office laboratory.
- **NPI# —** The National Provider Identifier number for the lab.
- **CLIA# —** The Clinical Laboratory Improvement Amendments number for the lab.
- **State Licenses —** The state license for the lab.

- **Lab Address** — Contact information for the lab, which includes the mailing address (with View Map capability).
- **Director's Name** — The name of the medical/lab director.
- **Tests Offered** — A tab with a list of tests offered by the lab. When selecting this tab, the list appears with the test title and a link to the lab test detail, the lab or manufacturer's test identification number, and a test description.
- Sharing Button – Select this button to send a request to the laboratory for consideration. The requesting lab will be notified if the request has been approved. For more information, see **My Organization: Sharing Lab Information.**

BROWSING BY DEX Z-CODE™

A Z-Code uniquely identifies each diagnostic test and enables mapping of a performing laboratory's test to that unique identifier.

Z-Code identifies are only visible to the organization that was assigned the Z-Code. To view Z-Codes via an approved sharing request, use the Lab Test Catalog or the Labs and Manufacturers Catalog.

Searching for Content in the Catalog

DEX™ Diagnostics Exchange provides several methods for searching for information in the catalog.

From the Browse Catalog window, search by using:

- **Breadcrumbs** — Shows the path taken to get to the current page. Click any item in the path to go back to that page.

> ⓘ NOTE: Use breadcrumbs to go back to a previous page. If using the browser's Back button (not recommended), the user will go back to the previous page without removing the breadcrumb from where the user departed. The breadcrumbs continue to list all pages visited; the list will not reset.

- **Change a search item** — Allows the user to select the catalog of lab tests, labs and manufacturers.
- **Search by keyword** — Allows the user to add a keyword. The system begins searching as typing begins in the text box.
- **Show All** — Click to clear all choices and start searching again with the entire list of available lab tests labs and manufacturers, or Z-Code identifiers, depending on the catalog page displayed.
- **View a page of returned results** — On the top and bottom right of the list, select the first page, previous page, next page, last page, or go to a specific page of returned search results.
- **Filter category list text box** — For the Diseases/Disorders category on the lab test and Z-Code pages, start to type a disease or a disorder in the text box to help filter the search list.

- **Search by category —** Click a category (or sub-category) from the list on the left navigation pane to view returned results by the selected category or sub-category. **See Using Categories to Filter a Search** for more information on categories.
- **View a specific number of returned results —** On the bottom left side of the list, select a number from the dropdown (15, 25, 50, and so forth). The selected number marks the number of returned results that appear. An indicator appears to the left of the dropdown showing the current range of returned results, for example Viewing 1-15 of 39.

USING CATEGORIES TO FILTER A SEARCH

When selecting a lab test or DEX Z-Code™, a list of categories appears on the left side of the browse window. Categories display in alphabetical order and display only those categories associated with the currently selected list of tests.

Use categories to drill down into a specific group of items. To further assist with filtering the Diseases/Disorders category, type a disease or disorder in the text box at the top of the category list. When opening a new browser window, the list of categories collapses to the first level and all available lab tests, labs, or Z-Code identifiers appear on the search list.

Drill down into the categories to refine the number of items that appear on the search list.

With each category and sub-category selection, the number of items on the search list gets smaller until the specific item or items appear, for example when selecting Diseases/Disorders > Anthrax.

CHAPTER 4 LAB INFORMATION

OBTAINING A DEX Z-CODE™

Obtaining a Z-Code:

1. Registering an organization
2. Adding a test
3. Requesting sharing with your reference lab

DEX™ Diagnostics Exchange enables users to register their lab or manufacturer. The process is somewhat different for each type.

After users register their organizations, they can **add their tests** and obtain their Z-Code identifiers. A separate Z-Code is required for each individual test.

Z-Code identifiers are assigned to entire tests, generally not to test components. If the test component, for example a gene, is not individually orderable, available to the public, or individually listed on a requisition form, then the component (gene) does not need its own Z-Code. However, a 20- gene panel, for example, would be a candidate for a single Z-Code.

Throughout the Z-Code assignment process, the test status changes from In Review, to Inactive, to Active. Once a test becomes Active, the lab or manufacturer administrator receives a notification via email. The administrator can then access the Z-Code, edit the test when needed, and view the test in the Catalog.

NAVIGATING THE ADD TEST FORM

These are the various components of the Add a New Test form:

- **Navigation pane** — The navigation pane marks the user's progress through the form. Note that the form consists of five sections. As the user completes each section, the label is marked with a green check mark.

  If a user is missing information for a section, the page can be saved as a draft, and the user can complete that section later. A red explanation mark appears next to a section that is incomplete.
- **Cancel** — This link allows a user to cancel the entire form before it is saved.
- **Save as Draft** — This button allows a user to save a draft of the form and come back to it later. The user might need to research or gather more information before completing the form.
- **Back** — This button allows the user to go back to the previous page of the form.
- **Next** — This button allows the user to go to the next page of the form.

ADDING A LAB TEST

Once a lab or manufacturer has registered with DEX™ Diagnostics Exchange, lab administrators can add a test or tests from their organization. Users begin by selecting Add Test from the splash screen or by selecting Edit Test in My Diagnostics Exchange.

- Adding a New Test: General Information
- Adding a New Test: Clinical Information
- Adding a New Test: Categories
- Adding a New Test: Facilities Information
- Adding a New Test: Financial Information
- Adding a New Test: Advanced Information

If users have questions about adding a test, they can download a worksheet by clicking the link below the Add Test button. The worksheet provides an explanation of each field in Add Test. In addition, the fields in Add Test have tool tips that users can hover over for additional information regarding each field.

Adding a New Test: General Information

The General page displays identifying information about the test that the user is adding.

To find Help that is specific to each section, click .

To enter general information about the lab test:

1. Complete the following fields, remembering that fields marked with a red asterisk are required.
    - **Test ID** — The identification number assigned to the test by the performing lab or manufacturer. A user can add up to 1024 characters in this field.
    - **Test Title** — The name of the test. Enter up to 1024 characters in this field.
    - **Are you the performing lab?** — Answer Yes or No. If you answer No contact DEX customer service for assistance.
    - **Test Description** — A description of the test. Enter up to 4000 characters in this field.
2. Continue to complete the following fields, remembering that fields marked with a red asterisk are required. To view the field requirements, click the tooltip icon next to the field.
    - **Molecular Component** — The molecular component for which this test is used. Enter up to 4000 characters in this field. Provide the gene(s), chromosomes and/or molecular component analyzed for the associated test/assay. Use italics and HGNC-approved nomenclature for gene symbols.
    - **Variants/Mutations/Alleles/Loci/Probes** — For every gene, chromosome, or molecular component listed in the Molecular Component field, provide the variants, mutations, alleles, loci, etc. for the associated test/assay. Enter up to 4000 characters in this field.

- **Mutation Type** — Identifies whether a lab test is germline, somatic, or both.
- **Germline:** An alteration in the DNA of germ cells (egg or sperm) inherited from a parent and passed on to offspring. Test is performed on a non-cancerous sample typically from a buccal swab or blood sample, to assess inherited DNA.
- **Somatic:** An alteration in DNA that occurs after conception and is present only in certain cells, not all cells. Testing may be performed on tumor DNA.
- **Both:** In certain situations, genetic testing for the same mutation may be performed on tumor tissue (somatic test) or non-cancerous sample (germline, such as blood or buccal swab).

3. After completing the page, click Next to continue with Adding a New Test: Clinical Information. If not continuing with the test, do one of the following:
    - Move to the previous page by selecting Back.
    - Cancel the add-test process by selecting Cancel.
    - Save the form as a draft by selecting Save as Draft. To return to the draft, go to the test list that displays in My Diagnostics Exchange.

ⓘ NOTE: Error icons appear when attempting to move to the next page without completing the current one.

Adding a New Test: Clinical Information

The Clinical page displays FDA information, whether the test is a device or a kit, and contributing test components.

To find Help that is specific to each section, click ?.

To enter clinical information about the lab test:

ⓘ NOTE: If a user selects Yes or Pending for FDA 510(k)/PMA, the Modifications to FDA Cleared/Approved Protocols, Device/Kit Manufacturer and Device/Kit Name fields are required.

1. Complete the following fields, remembering that fields marked with a red asterisk are required:
    - **FDA 510(k) /PMA** — An indication of whether the test has been FDA cleared or approved. Select Yes if the test has been approved, or No if it has not. Select Pending if the test is still in process. When a user selects Yes, the Device/Kit field below defaults to Yes, and information for the Device/Kit manufacturer and name are required.
    - **FDA Document #** — The document number for the test if it has been FDA cleared or approved or is pending. This field is enabled only if the FDA 510(k) /PMA field is defined as Yes or Pending.
    - **Modification to FDA Cleared/Approved Protocols** — Yes or No. Indicates whether a lab has made any changes to a test after the FDA has cleared or

approved the device. If Yes for modified FDA kits, provide details describing modifications below in the contributing components field. Device/Kit — An indication of whether a device or kit is used for the test or assay. Select Yes if a device or kit is used, or No if it has not.

- **Device/Kit Manufacturer —** Indicates the name of the manufacturer of the device or kit. This field is enabled only if the Device/Kit field is defined as Yes. Enter up to 1024 characters in this field.
- **Device Kit Name —** The name of the device or kit, if one is used. Enter up to 128 characters in this field. This field is enabled only if a device or kit is being used. The Device/Kit name should include the entire marketed name of the kit or device being used to perform the test. Do not abbreviate any kit or device name. The Device/Kit Name field is not for instrument platforms.
- **Contributing Components —** List all the components/analytes/formulas/calculations/biomarkers, and so forth that make up the test/assay. Inclusion of Standard Operating Procedure (SOP) is permitted in this field. Formulas, calculations, biomarkers, and so forth need only be identified as such. Do not include intellectual property. A user can add up to 2048 characters in this field.
- For modified FDA kits, provide details describing modifications to this field.

ⓘ NOTE: Error icons appear when attempting to move to the next page without completing the current one.

2. After completing the page, click Next to continue with **Adding a New Test: Categories.** If not continuing with the test, do one of the following:
   - Move to the previous page by selecting Back.
   - Cancel the add-test process by selecting Cancel.
   - Save the form as a draft by selecting Save as Draft. To return to the draft, go to the test list that displays in My Diagnostics Exchange.

Adding a New Test: Categories

The Categories page displays categories of information that can be associated with the test being added. Categories are listed in alphabetical order. Collapse each section by clicking the up arrow on the right of the section to hide the options. Expand each section by clicking the down arrow on the right of the section to show more options.

To find Help that is specific to each section, click .

If a category is not listed, then add a suggestion. To do this:

1. Click the Add a Suggestion link below the appropriate category.
2. Type the suggestion in the Enter Suggestion text box.
3. Click Add to add a suggestion or Cancel to cancel the suggestion. The suggestion needs to be approved by DEX.

To enter categories for your lab test:

1. Complete the following fields, moving selections from the left column to the right by selecting Add. Select Remove to return selections to the left column. Also, remember that fields marked with a red asterisk are required:
   - **Test Type —** The type of test, such as Diagnostic or Monitoring.
2. **Disease/Disorders —** Search for the disease or disorder by scrolling through the alphabetical list. Choose all applicable Diseases/Disorders. If the desired category is not on the list, add a suggestion. Continue adding the following category for your lab test:
3. **Methodology —** Choose all applicable methodologies for the test. If the desired category is not on the list, add a suggestion. Continue to add the remaining fields:
   - **Medical Specialties —** Choose the Medical Specialties that correspond to the developed test. Choose all applicable Medical Specialties. If the desired category is not on the list, add a suggestion.
   - **FDA —** Choose the applicable FDA category: 510(k) or PMA.

   ⓘ NOTE: Error icons appear when attempting to move to the next page without completing the current one.

4. After completing this page, click Next to continue with **Adding a New Test: Financial Information,** unless adding a test for a parent organization, then select **Adding a New Test: Facilities Information.** If not continuing with the test, do one of the following:
   - Move to the previous page by selecting Back.
   - Cancel the add-test process by selecting Cancel.
   - Save the form as a draft by selecting Save as Draft. To return to the draft, go to the test list that displays in My Diagnostics Exchange.

Adding a New Test: Facilities Information

The Facilities page displays a list of available facilities assigned to a parent organization by the parent organization administrator. Move a facility to the Selected column if that facility performs the lab test being added or you will be using the facility NPI for billing purposes.

To associate a lab test with a facility that performs that test:

1. Highlight the facility in the Available column and then select the Add > button.

   When a lab administrator moves a facility from the Available column to the Selected column, the Test ID displays for that facility. The Test ID is an identifier that is internal to the specific facility.

2. Edit the Test ID field if necessary.

To move multiple facilities from the Available column to the Selected column:

1. Highlight all the facilities and then select the Add All >> button.
2. Change the test IDs as needed.

ⓘ NOTE: Facilities can only be removed **before** the test is submitted. Once the test is published only a super user can remove a facility from a test.

To move a facility from the Selected column back to the Available column:

- Highlight a facility and then select the < Remove button.

To move multiple facilities from the Selected column back to the Available column:

1. Highlight all the facilities and then select the << Remove All button.
2. After completing the page, click Next to continue with Adding a New Test: Financial Information. If not continuing with the test, do one of the following:
    - Move to the previous page by selecting Back.
    - Cancel the add-test process by selecting Cancel.
    - Save the form as a draft by selecting Save as Draft. To return to the draft, go to the test list that displays in My Diagnostics Exchange.

Adding a New Test: Financial Information

The Financial page displays information regarding CPT® and HCPCS codes associated with the test being added.

To find Help that is specific to each section, click .

To enter Financial information about the lab test:

Complete the following fields, remembering that fields marked with a red asterisk are required:

- **Add CPT® Codes (Current)** — Provide the CPT® code(s) used to bill or place the test/assay on a claim.
- **Add MolDX Recommended CPT® Codes —** This CPT code is recommended for billing on the claim to your MAC. The code will be provided by the MolDX® Program (Administered by Palmetto GBA). You will receive a separate email from DEX after Z-Code assignment if your test is updated with a MolDX Recommended CPT code. P
- **Add HCPCS —** Provide the HCPCS code used to bill or place the test/assay on a claim.
- **Price ($) —** Provide the list price available to the general public.

To add CPT® or HCPCS codes to this page:

1. Start to type the number for the CPT® or HCPCS code.

    A window appears with a list of CPT® or HCPCS codes that match the numbers being typed.

2. Select a CPT® or HCPCS code from that window, and then add the number of units from the new window that appears.

   The CPT® or HCPCS code, units of service number, and the description appear on the form. If needed, remove any CPT® or HCPCS code by clicking Remove.

3. Repeat the process to add more CPT® or HCPCS codes.

ⓘ NOTE: Error icons appear when attempting to move to the next page without completing the current one.

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4. After completing this page, click Next to continue with **Adding a New Test: Advanced Information**. If not continuing with the test, do one of the following:
   - Move to the previous page by selecting Back.
   - Cancel the add-test process by selecting Cancel.
   - Save the form as a draft by selecting Save as Draft. To return to the draft, go to the test list that displays in My Diagnostics Exchange.

Adding a New Test: Advanced Information

The Advanced page displays the fields containing advanced information, such as whether the test goes by an alias, has an algorithm, whether there is a comparable test, and so forth.

To find Help that is specific to each section, click ?.

To enter advanced information about the lab test:

1. Complete all the fields, remembering that fields marked with a red asterisk are required.
   - **Algorithm (required field)**— Yes or No. Indicate whether the test uses an algorithm. An algorithm is defined here as a clinical assessment consisting of multiple variables (e.g. patient-specific and/or population measures, laboratory assays) combined into a single score or indicator of health status
   - **Comparable Assay** — May be defined as Lab Developed Tests (LDTs), FDA-approved kits, or commercially available assays that provide a similar diagnostic result. Enter up to 2048 characters in this field.
   - **Specimen Instructions (required field)** — Indicates specimen information associated with the test. Enter up to 4096 characters in this field.

2. Continue completing the fields below.
   - **Handling Instructions** — Indicates specific instructions about how the specimen(s) needs to be handled. Enter up to 4096 characters in this field.
   - **Estimated Turn Around Time** — Provides the estimated turnaround time for the final test or assay result to be available to clinicians and downstream systems. This field is used with the next field "Estimated Turn Around Time Duration." To demonstrate how the two fields work together, if a patient has a

BRCA genetic test and the estimated turnaround time for receiving test results is 2 weeks, the user would enter "2" in this field and "weeks" in the next field. In addition to entering single numerals, this field allows users to add a range of numbers, such as "3-5."

- **Estimated Turn Around Time Duration —** This field is used with the previous field "Estimated Turn Around Time". To demonstrate how the two fields work together, if a patient has a BRCA genetic test and the estimated turnaround time for receiving test results is 2 weeks, the user would enter "weeks" in this field, and "2" in the previous field.
- **Patient Instructions —** Indicates patient instructions associated with the test. Enter up to 4096 characters in this field.

3. Continue completing the following fields, which contain criteria set by a payer who is assessing the test for coverage determination.
    - **Clinical Validity —** The extent to which a test accurately predicts the risk of an outcome and to which it is able to separate patients with different outcomes into separate risk classes. Enter up to 4000 characters in this field.
    - **Precision —** The chance that a subject testing positive has the condition being tested for. Enter up to 2000 characters in this field.
    - **Analytic Sensitivity —** The smallest amount of substance in a sample that can accurately be measured by an assay. Enter up to 4000 characters in this field.
4. Continue completing the remaining fields. These fields also contain criteria set by a payer who is assessing the test for coverage determination.
    - **Analytic Specificity —** The ability of an assay to detect an organism or substance. Enter up to 4000 characters in this field.
    - **Positive Predictive Value —** The probability that a patient with a positive test result really does have the condition for which the test was conducted. Enter up to 2000 characters in this field.
    - **Negative Predictive Value —** The probability that a patient with a negative test result really is free of the condition for which the test was conducted. Enter up to 2000 characters in this field.

ⓘ NOTE: Error icons appear when attempting to move to the next page without completing the current one.

5. After completing all required information for a newly added test, review the entered information before submitting for review. For more information, see **Reviewing a New Lab Test**. If not submitting the test, do one of the following:
    - Move to the previous page by selecting Back.
    - Cancel the add-test process by selecting Cancel.
    - Save the form as a draft by selecting Save as Draft. To return to the draft, go to the test list that displays in My Diagnostics Exchange.

Reviewing a New Lab Test

Once the pages are complete for adding a new test, the lab administrator can review test values before submitting it to DEX™ Diagnostics Exchange for a DEX Z-Code™. To access the Review and Submit preview page, click Review and Submit at the bottom right of the Adding a Lab Test: Advanced page.

ⓘ NOTE: If one or more of the required fields are not complete, the Review and Submit button will not be selectable.

The Review and Submit page appears displaying entered information. The red asterisks denote required fields.

A lab administrator should review this preview page carefully to make sure that the field values are as accurate as possible. To change the value of a field or fields, click the Return to Edit link at the bottom right of the page and access the page or pages to update. To print a draft of the review summary, select Print Draft at the top right of the page. The lab administrator can select Submit when sure that the pages are satisfactorily complete. For more information on submitting the lab test for a Z-Code identifier, see **Submitting a New Lab Test**.

Submitting a New Lab Test

The Submit button will activate once all information is complete, green check marks appear next to all criteria pages, and the review has been performed.

When you select Yes to submit the test, the Confirm Submit window appears.

- Select Yes to submit the test and confirm the changes.

ⓘ **Note:** It can take up to 45-business days for a test to appear in the catalog once submitted.

- If you select No, do one of the following:
- Cancel the submission by clicking Cancel.
- Save the form as a draft by selecting Save as Draft. To return to the draft, go to the test list that displays in My Diagnostics Exchange. Delete the form, if desired, by opening the draft and selecting Delete Draft on the left side of the form.

After DEX™ Diagnostics Exchange reviews the submitted test and assigns a DEX Z-Code, the lab will receive email notification when it is active.

CHAPTER 5: MY DIAGNOSTICS EXCHANGE

MANAGE LAB TESTS, DASHBOARD, USERS AND FACILITIES:

Lab Tests:

To view your lab tests from the DEX™ Diagnostics Exchange Home page:

1. Select the My Diagnostics Exchange menu option.
2. View your tests and their Status.

   Draft: Lab test has been started, but not submitted or DEX has reviewed the test and more information is requested.

   In Review: Lab test has been submitted for DEX review

   Inactive: Test has been processed and will be active with a Z-Code in a few days OR tests has been retired.

   Active: Test has been assigned a Z-Code and is Active for use.

3. Test Edits: From the list on the Lab Tests tab, select the lab test to edit.

   Click the Edit button to the right of the lab test window.

   Update the information on each tab as needed.

   To Retire a test: Set the End field to inactivate the test. If setting an ending date, a reason for inactivating the test, such as retired, must be included. Effective date ranges are inclusive, so if the end date is today's date then the test won't show as inactive until the next day.

- Retire a Test: When finished editing, select Submit, Save or Cancel.

Submit — Selecting Submit results in one of two options:

- Edits do not have an impact on the DEX Z-Code™ and as a result edits will immediately display in the catalog.
- Test will be In Review and cannot be edited. The test is grayed out and cannot be selected or opened. Once the review is complete, the test will be completely viewable in the catalog.

Save — Select Save and then select Yes for the test to be saved as a Draft for additional editing and to be published at another time.

- The status of the test becomes Draft.
- The test is visible, but not accessible, in the catalog.
- The lab administrator can view the test with a watermark from My Diagnostics Exchange.

ⓘ NOTE: The DRAFT watermark appears in a different font, size, and/or angle depending on the supported browser used.

Each time edits are saved, DEX creates a new version. For more information about versions, see **"Saving Edit Versions".**

- Select Save and then select No, to return to the edit screen to make or review changes.

Cancel — Select Cancel if not saving changes.

Saving Edit Versions

It is possible to save a draft of lab test edits to complete at another time. Each time a user saves a draft, DEX™ Diagnostics Exchange assigns a version number incrementally. The version feature allows a user to track and identify changes that occurred to a test. For more information on saving a draft, see **Editing a Lab Test.**

The Activity Log, at the bottom of the Lab Test window, begins recording the test from the time it is entered into DEX, and it records all additions and edits to a test. In addition, the log keeps track of draft versions.

If an edit needs to be reviewed, it will return to Draft mode so that a user can update changes.

To view draft versions:

1. From the lab, open a lab test that is currently being edited.
2. Open the Activity Log tab at the bottom of the Lab Test window.

The Activity Log appears in table form with the following columns:

- **Item** — The item that was modified, example "Patient Instructions or Status."
- **Action** — The specific action that took place with a description of the value prior to a change to the modification made to the item, example "Modified 'None' to 'Genetic forms must be submitted.' "
- **Date** — The date and time that the edit was made.
- **Version** — The version number assigned to the action listed.
- **User** — The user name of the person who made the edit. If a change is made by a DEX user, the field displays super user instead of an actual name.

COVERAGE INFORMATION

Viewing Coverage History

To help determine the coverage of a test for a given date or date of service, a lab administrator can view the history of changes to the coverage.

1. Log on to DEX™ Diagnostics Exchange.
2. When viewing coverage history, access the Coverage tab in one of two ways:

   A. From the catalog, select Lab Tests and then select a test, or
   B. Access My Diagnostics Exchange and from the list on the Lab Tests tab, select a lab test.

3. Scroll to the bottom of the test and select the Coverage tab, if it is not already selected.
4. In the Coverage column, click the clock icon to view the coverage history.

   A popup appears showing the coverage and date applied for the selected payer and plan.

5. Move the pointer away from the popup to close it.

USING THE LAB DASHBOARD

The lab dashboard allows lab administrators to view a visual representation of the lab tests they have submitted to DEX™ Diagnostics Exchange. On this dashboard, the tests are grouped by Status, such as Active; and by Active Test Type, such as Diagnostic.

The dashboard specifies the number of tests within each status and, for active tests, within each test type, so that administrators can see, at a glance, where most of the activity is taking place.

In addition to the visual representation on the right side of the tab, administrators can access the Message Center, add a new test, and view a list of the most recent coverage, all from the left side of the tab.

When the lab administrator selects My Diagnostics Exchange, the Dashboard tab opens by default. The following information appears on the lab dashboard.

- **Activity** —This header indicates that the information that appears within this section are actions that a lab administrator can perform, such as adding a test.
- **Lab Tests** — This header marks a section of items that a lab administrator can view to obtain a quick snapshot of how the lab tests are distributed within DEX, by status and by active type.
- **Message Center Link** — This section specifies the number of new messages for the lab. Click the New Messages link to access the Message Center.
- **Date** — The date appears under the Activity header on the left side of the tab, and under the Lab Tests header on the right side of the tab. The date displayed is today's date in a Day, Month, DD, YYYY format with the day and month spelled out.
- **Add Test** — This button accesses the Add Test pages so that a lab administrator can add a new test from the dashboard. When the lab administrator completes these pages, or saves them as a draft, the number for that new test's status advances by one on the donut chart and the legend. When the lab administrator specifies a test type for the new test, the number next to that type advances by one.
- **Coverage Changes** — This section displays the most recent changes to lab test coverage.
- **Donut Chart** — A visual display of all the tests that this one lab has submitted to DEX, grouped by status. The number in the middle is the total number of tests.

- **Legend** — A visual display of all the tests that this one lab has submitted to DEX, listed by status. Next to each status value is the number of tests within that status. The numbers in this section add up to the total number in the middle of the donut chart.
- **Active Test Types** — A visual display showing how all the active tests for this one lab are grouped according to test type. The numbers in this section add up to the total number of active tests for this lab.

USERS TAB

1. Select the Users tab.
2. Select Add User Record.
3. Enter the following information:
    - Name
    - Email. The email address will be the user name.
    - Job Title
    - Clinical Credentials (required for one user per organization)
4. Assign permission. Lab User or Lab Administrator. Note, Lab User role has fewer permissions. For more information on how permissions are assigned, see **About Permissions**.
5. Select Save and Send Welcome Email to save the new account and to notify the new user that the account has been created.

ⓘ NOTE: The status on the user profile is associated with its organization, which is allowed only two active users at a time. A lab administrator can edit the user profile to associate the user's credentials with its organization. However, the administrator cannot edit a Pending user. In addition, only an administrator can inactivate a user. For more information on the user profile, status, credentials, and how they are associated with their organization, see **User Profiles Associated with Organizations.**

CHAPTER 6 MY ORGANIZATION

ABOUT MY ORGANIZATION

Users can manage the following settings for their organization by selecting My Organization from the dropdown below the username. Click a link below for more information about each group of settings:

- My Organization: General Information
- My Organization: Contact Information
- My Organization: Sharing Lab Information
- My Organization: Test Privacy
- My Organization: Participation
- My Organization: Activity Log

MY ORGANIZATION: GENERAL INFORMATION

This tab displays the following information:

- Name, website URL (for a manufacturer), and laboratory type for the organization.
- Number of users currently using DEX™ Diagnostics Exchange.
- List of user names, last version of the DEX Z-Code™ Terms & Conditions accepted by each listed user, and the date and time they were accepted.
- The credentials (NPI number, CLIA number, and expiration date of the CLIA number). A parent administrator will not see the NPI, and CLIA information for the parent organization.
- State license number(s), expiration date for the license number(s), and the ability to add or delete numbers from the list.

Remember to click the Save button after completing the changes on this tab.

MY ORGANIZATION: CONTACT INFORMATION

This tab lists address, email, phone, fax information, credentials, and the active users assigned to the lab administrator and clinical resource contacts. See **User Profiles Associated with Organizations** for more information on the user profile status and credentials and how they are associated with the organization.

Remember to click the Save button after completing the changes on this tab.

MY ORGANIZATION: SHARING LAB INFORMATION

Sharing is a feature within the DEX™ Diagnostics Exchange that allows a client lab to see the details of a performing lab's test information and Z-Code for send out tests that require a DEX Z-Code for billing.

Ⓘ NOTE: The Sharing feature is available only to labs that perform testing. It is not intended for organizations that sell tests.

DEX provides a sharing feature for performing labs who want to share their Labs & Manufacturers catalog with client labs. The performing lab can select either Global or Discrete sharing.

- **Global sharing —** Enables the performing lab to share their information immediately and without approval to the requesting client lab.
- **Discrete sharing —** Enables the performing lab to decide whether to approve the client lab's sharing request or not.

All sharing labs must be registered with DEX and have active tests in the catalog.

For more information on how to use the Sharing feature, see the following topics:

- Making a Sharing Request
- Reviewing a Sharing Request

Making a Sharing Request

To make a request for sharing:

1. For requesting client labs, go to the Labs & Manufacturers catalog and select the lab from which to request sharing.
2. Select the Request Sharing button on the upper right of the Lab Detail screen.
3. Select Send Request when the message appears asking the lab if it would like to request information sharing with this lab. The lab can always select Cancel if it changes its mind.

If the performing lab selected Global sharing, the client lab will be able to view shared information from the performing lab immediately with no need for an approval review from the performing lab.

If the performing lab selected Discrete sharing, the client lab will receive the following message:

Thank you, your request has been submitted. You will receive notification upon approval of your request. Click OK.

The requesting lab can find out the performing lab's decision to share information in two ways. First, the lab can go to the Sharing tab within their My Organization section to view the performing lab's decision, marked by an Approved, Pending, or Not Approved icon.

Second, the requesting lab can go to the Labs & Manufacturers catalog to view the Approved, Pending, or Not Approved icons next to the labs from which they requested sharing approval.

If the performing lab approves sharing for the requesting lab, the client lab can search for their send out tests in either the Lab Tests Catalog or the Labs and Manufacturers Catalog.

In the Lab Tests Catalog, Use the Search bar to enter the Lab Name along with the Test Code or Test ID. Since the Lab Tests Catalog is all inclusive, this will narrow down the search results. At this time, searching by CPT is not available.

Alternatively, use the Labs and Manufacturers Catalog> Enter the lab name in the search field> Click the lab and view test menu. Click on the send out test and find the Z-Code and CPT code. Note the MolDX Recommended CPT code is the CPT code that should be used on claims submitted to a MAC.

Reviewing a Sharing Request

To review the sharing request:

1. Go to the Sharing tab within the My Organization section.
2. View the incoming request at the bottom of the page.
    A. If the lab has selected Global Sharing, then the request is automatically approved, and the requesting lab has access to the shared information.
    B. If the lab has selected Discrete Sharing, then after reviewing the request, select either Approve or Do Not Approve.
3. The requesting lab will receive a notification icon on the Sharing tab within My Organization and in the Labs & Manufacturers catalog.

Information that Labs Can Share

The sharing lab will provide information for the following fields with the lab that requested shared information:

- Lab Test Name
- Lab Test ID
- Lab/Mfr Name
- CPT® Codes
- MolDX Recommended CPT® Code
- DEX Z-Code™ identifiers
- Lab Test Description
- Methodology
- FDA 510(k)/PMA
- FDA Document #
- Handling Instructions
- Handling, Estimated Turnaround Times

- Specimen Information
- Patient Instructions

In addition, any of the following fields will be public if the sharing lab chooses them on the Test Privacy tab in their My Organization section:

- Price
- Comparable Test/ Assay
- Molecular Component
- Gene Variant/Mutation/Allele
- Mutation type
- Algorithm
- Mods to FDA Cleared/Approved
- Contributing Components
- Device/Kit Information
- Gene
- Clinical Validity
- Precision
- Analytic Sensitivity
- Analytic Specificity
- Positive Predictive Value
- Negative Predictive Value

Discontinuing Sharing with an Approved Lab

Both client and performing labs can choose to discontinue sharing with another lab.

To discontinue sharing with an approved lab:

1. Contact DEX.Customer.Service@PalmettoGBA.com.
2. Notify the lab that information sharing has been discontinued.

MY ORGANIZATION: TEST PRIVACY

On the left side of this tab is a list of information that is visible to the public and cannot be made private. On the right side are fields that a lab administrator can make private so that they are not visible to users or public so that they are visible to users. Users can select Public or Private radio buttons for any of the fields list and then confirm Yes or No as to whether they want to make the changes.

For a Yes answer, the Test Privacy elements indicated as Public are immediately visible to the public, display on the Advanced tab, and are recorded in the My Organization Activity Log for lab administrators.

For a No answer, users are returned to the Test Privacy tab.

Remember to click the Save button after completing the changes on this tab.

MY ORGANIZATION: PARTICIPATION

This tab lists the payers that allow a lab administrator to submit coverage determination requests. Payers can be added to the list by selecting a payer from the Available Payers column and clicking the Add button to move the payer to the Selected Payers column.

Remember to click the Save button after completing the changes on this tab.

MY ORGANIZATION: ACTIVITY LOG

The Activity Log tab records edits, deletions and additions to organization information including AMA participation, payer options, and test privacy options. Each row includes a description of the activity that was performed, the action taken, the date and time that the activity was updated, and the name of the user who performed the activity.

EDITING AN ORGANIZATION

When lab administrators log into DEX™ Diagnostics Exchange they can select My Organization from the dropdown below the username.

Accessing My Organization opens a screen with the following tabs:

- My Organization: General Information
- My Organization: Contact Information
- My Organization: Sharing Lab Information
- My Organization: Test Privacy
- My Organization: Participation
- My Organization: Activity Log

Refer back to the above topics for more information about the organization content that lab administrators can edit within that tab.

CHAPTER 7 PARENT ORGANIZATIONS

PARENT ORGANIZATION OVERVIEW

DEX™ Diagnostics Exchange can provide a parent entity for organizations with multiple facilities. A parent is an overarching entity for the many facilities (performing labs) that are wholly owned subsidiaries of a parent organization. Building a parent organization entity facilitates a single point of data entry for the entire organization and identifies all facilities associated with their parent organization throughout the DEX catalog (the catalog).

The parent organization structure includes the following components:

Parent organization — An overarching shell to which facilities are associated. Parent entries do not list CLIA/NPI or licensing information, and cannot be accessed in the catalog.

Facility — A lab within a parent organization that performs one or more tests listed in the DEX catalog. Facility detail is listed in the catalog.

Lab Test — A diagnostics test that a parent organization administrator has added to the catalog with a list of facilities that perform that test.

ⓘ NOTE: Each facility within a parent organization can assign a test code identifier that can be the same among all facilities, or can be different.

DEX Z-Code™ — A Z-Code is assigned by DEX when a lab adds a test to the catalog. Unlike the lab's internal test ID, which can vary from facility to facility, each lab test has just one unique Z-Code that is used to identify that test throughout DEX.

To request a parent organization, a lab can send contact information for two parent lab administrators who will assign facilities to the parent organization and manage all lab test and organization information for all facilities. After DEX sets up the parent organization, the parent lab administrators will receive an email with their login name and a link for setting up a password.

ⓘ NOTE: If an organization is registered as a standalone but fits the definition of a parent as described above, contact DEX.Customer.Service@changehealthcare.com.

The following list displays instructions and other information about a parent organization:

- "Adding Facilities to the Parent Organization"
- Adding a New Test: Facilities Information
- Viewing a Parent Organization and Associated Facilities in the Catalog
- Editing an Organization
- Editing Facilities for a Parent Organization

ADDING FACILITIES TO THE PARENT ORGANIZATION

Parent lab administrators and DEX™ Diagnostics Exchange super users are the only ones who can add facilities to a parent organization. These facilities display on the Facilities page when adding a new test.

The user adding the test can add one or more facilities. For more information, see **Adding a New Test: Facilities Information.**

To assign facilities to a parent organization:

General Info tab

1. From My Diagnostics Exchange, open the Facilities tab.
2. Select the Add Facility button.

The Create New Facility Organization window opens to the General Info page.

ⓘ NOTE: The exclamation points next to the two tabs on the Create New Facility Organization page are error icons. Because this is a new facility, the error icon indicates that required information on the tab has not yet been added. If the error icon appears after completing the information on either tab, click Save to access a red panel explaining the issue.

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3. Complete the following information on the General Info tab:
    - **Name** — The facility name.
    - **Website** — The facility website address.
    - Laboratory Type — Describes the type of laboratory such as Physician office laboratory or Hospital affiliated laboratory
    - **DEX Z-Code™ Terms & Conditions — Lists** the most current version of the Z-Code Terms & Conditions read by the parent lab administrator and the date and time it was read. (read only)
    - **CLIA** — The CLIA number for the facility. The number entered is validated for accuracy and an error message could appear. This is a required field.
    - **CLIA Expiration Date** — Use the calendar, remembering that >> advances the year, and > advances the month.
    - **State License** — Optionally enter the state license for the lab.
    - Expiration Date — Optionally enter the expiration date of the lab's state license. Use the calendar, and keep in mind that >> advances the year, and > advances the month.
    - **Action** — Select Add to record the state license information. The entered information moves down a row, and enables deletion of the row. There is no limit to the number of state licenses to enter.
4. Save the facility information by clicking the Save button, or cancel it by clicking the Cancel button.
5. Open the Contact Info tab and continue with the instructions below.

Contact Info tab

This Contact Info tab lists address, phone, and fax information for the lab administrator and clinical resource contacts at the new facility being added to the parent organization. This tab page is similar to user profiles being associated with organizations. For more information, see **User Profiles Associated with Organizations.**

The contact at the top left of the page can be the same as the Administrator User or different. The same is true of the Medical/Lab Director Contact which can be the same as the Clinical Resources Contact or different. The clinical resource should be someone with a medical background who can answer clinical questions pertaining to tests.

To populate contact information for the Administrator User, Medical/Lab Director Contact, and Clinical Resource Contact, check the Inherit values from parent organization check box with each section. The inherited values come from the parent organization. The parent lab administrator can change information for the parent organization via the My Organization when logged in.

ADDING A NEW TEST: FACILITIES INFORMATION

The Facilities page displays a list of available facilities assigned to a parent organization by the parent organization administrator. Move a facility to the Selected column if that facility performs the lab test being added.

To associate a lab test with a facility that performs that test:

1. Highlight the facility in the Available column and then select the Add > button.

   When a lab administrator moves a facility from the Available column to the Selected column, the Test ID displays for that facility. The Test ID is an identifier that is internal to the specific facility.

2. Edit the Test ID field if necessary.

To move multiple facilities from the Available column to the Selected column:

1. Highlight all the facilities and then select the Add All >> button.
2. Change the test IDs as needed.

ⓘ NOTE: Facilities can only be removed **before** the test is submitted. Once the test is published only a super user can remove a facility from a test.

To move a facility from the Selected column back to the Available column:

- Highlight a facility and then select the < Remove button.

To move multiple facilities from the Selected column back to the Available column:

1. Highlight all the facilities and then select the << Remove All button.
2. After completing the page, click Next to continue with **Adding a New Test: Financial Information.** If not continuing with the test, do one of the following:
   - Move to the previous page by selecting Back.

- Cancel the add-test process by selecting Cancel.
- Save the form as a draft by selecting Save as Draft. To return to the draft, go to the test list that displays in My Diagnostics Exchange.

EDITING FACILITIES FOR A PARENT ORGANIZATION

Administrators for parent organizations can edit associated facilities. This topic explains how to edit facilities. To edit other parts of a lab test, refer to **Editing a Lab Test**.

To edit a facility from the DEX™ Diagnostics Exchange Home page:

1. Select the My Diagnostics Exchange menu option.
2. Select the Facilities tab.
3. Select the Facility to edit.

   The Edit Facility Organization page opens defaulted to the General Info tab.

4. Edit any of the fields on this tab except for the Organization Type, User Count, and DEX Z-Code™ Terms & Conditions. The Name, Laboratory Type, NPI #, and CLIA # fields are populated when a user opens this tab for editing.
5. After completing edits, select the Contact Info tab, if needed.
6. Edit any of the fields on this tab. If the Administrator User and Clinical Resource Contact Information sections are greyed out, un-check the Inherited box for the section(s) to edit, then change the Administrator User and Clinical Resource to any active administrator associated with the parent organization.
7. To check activities performed on facilities, select the Activity Log tab. The activity log displays the item being modified, the action performed on the item, the date and time that the activity occurred, and the name of the user who performed the activity.
8. When finished editing, select Save or Cancel.

   Save — Select Save and then select Yes to save your changes. Select No if you do not want to save your changes.

   Cancel — Select Cancel if not saving changes.

VIEWING A PARENT ORGANIZATION AND ASSOCIATED FACILITIES IN THE CATALOG

DEX™ Diagnostics Exchange displays parent organizations and their associated facilities in the Lab Tests, Labs & Manufacturers, and DEX Z-Code™ identifiers catalogs. To identify parent organizations in the catalog, the parent organization has a plus icon next to it.

When a user clicks the plus sign, a list of associated facilities, and the number of facilities, for that parent organization display in the row.

Each facility listed is a link that a user can click to access detail for that facility.

In addition to the Lab Tests catalog, uses can view parent organization/facility relationships in the Labs & Manufacturers and Z-Codes catalogs.

Users can view parent organizations and their associated facilities by accessing Z-Code detail, scrolling down to the bottom of the page, and viewing the list of tests offered.

CHAPTER 8 MANAGING A PERSONAL ACCOUNT, USERS, AND PERMISSIONS

ADDING A NEW USER

To add a user:

1. Log in to DEX™ Diagnostics Exchange.
2. Select the My Diagnostics Exchange menu option.

> ⓘ NOTE: A user must have permission to add a new user. To check permissions, select My Account from the dropdown below the username, and view the list of activities that can be performed within the role. If the "Manage your users" activity is not listed, then that user does not have permission to add a user.

3. Select the Users tab.
4. Select Add User Record.

   The Create New User window appears.

5. Enter the following required information:
   - Name and Email. The email address will be the user name.
   - Status includes Active, Inactive, Pending.
6. Optionally, select Save and Send Welcome Email to save the new account and to notify the new user that the account has been created.
7. Assign permissions by clicking the radio button to the right of only one role that can be assigned to a user. For more information on how permissions are assigned, see **About Permissions**.
8. Select Save when done, or Cancel to not save the changes.
   - Selecting Save automatically saves the user to the User list.
   - Selecting Cancel opens the Confirm Close window prompting the user to confirm the decision, because unsaved changes will be lost.

   > ⓘ NOTE: The status on the user profile is associated with its organization, which is allowed only two active users at a time. A lab administrator can edit the user profile to associate the user's credentials with its organization. However, the administrator cannot edit a Pending user. In addition, only an administrator can inactivate a user. For more information on the user profile, status, credentials, and how they are associated with their organization, see **User Profiles Associated with Organizations**.

EDITING USER INFORMATION

To edit user information:

1. Log in to DEX™ Diagnostics Exchange.
2. Select the My Diagnostics Exchange menu option.

ⓘ NOTE: Editing user information requires specific permission. To check whether permission is granted for this activity, select My Account from the dropdown below the username, and view the list of activities to perform within the role. If the "Manage your Users" activity is not listed, then there is no permission to perform this task.

3. With the proper permission, select the Users tab to access the list of users for the lab.
4. From the list on the Users tab, select the Edit link to the left of the user whose information to edit.

   The Edit User window appears defaulted to the User Details tab.

5. Update the information on this window as needed. In this window, the lab administrator can add credentials to the user profile.

   ⓘ NOTE: A lab administrator can edit the user profile to associate the user's status and credentials with its organization. For more information on the user profile status and credentials and how they are associated with their organization, see User Profiles Associated with Organizations.

6. After editing, select Save to save the work, otherwise select Cancel.
7. Select the Activity Log tab to view changes to this user's account.

EDITING INFORMATION FOR A PERSONAL ACCOUNT

To edit information for a personal account:

1. Select My Account from the dropdown below the username.

   The My Account window opens defaulted to the User Details tab. Account information is populated with values added by the administrator, when adding the new account. That information along with current permissions are view only.

2. The user can reset the password, as needed. Passwords must be 8 to 20 characters long and contain an upper-case letter, a lower-case letter, and a number.

   Also, view the last few times the user accepted the DEX Z-Code™ Terms & Conditions.

   ⓘ NOTE: The profile, status, and credentials display as contact information in the organization. For more information on the user profile, status, credentials, and how they are associated with their organization, see **User Profiles Associated with Organizations**.

   ⓘ NOTE: Users cannot inactivate their own accounts. To inactivate one's own account, contact another administrator on the account, or contact a DEX representative at DEX.Customer.Service@PalmettoGBA.com.

3. Select the Activity log tab to view changes to the account.

USER PROFILES ASSOCIATED WITH ORGANIZATIONS

The Administrator User and Clinical Resource Contact are created when registering an organization in DEX™ Diagnostics Exchange. User accounts for these roles have a Pending status on the Contact Information page from within My Diagnostics Exchange until those users' accounts are activated. This topic explains how to manage the Contact Information page.

When a User Profile is Active

If a user's account is Locked or Inactive, the Administrator User can select the Active status on the user's account to activate it. Once activated, users can be assigned as Administrator User or Clinical Resource Contact roles through the Change To dropdown list for each role.

When a User Profile is Pending

If the user assigned to the Clinical Resource Contact role during registration is pending, the Administrator User can still make changes to the organization on the Contact Information page, but that pending user will not appear in the Clinical Resource Contact Change To dropdown list until that user's account is activated. In addition, if the pending user's account is not activated within 30 days, DEX inactivates that user's account automatically.

ⓘ NOTE: A pending user account that is automatically inactivated after 30 days only applies to the Clinical Resource Contact, not to the Administrator User.

The inactive user's name still appears in the Clinical Resource Contact section and the Administrator User can make changes to the organization's Contact Information page, but cannot make an Inactive status Pending.

If the Clinical Resource Contact and the Administrator User are the same person, both assignments become inactive and an error displays on the Contact Information page. Contact a Super User via email at (DEX.Customer.Service@palmettogba.com) to re-activate the inactive Administrator User's account.

When a User Profile is Inactivated

When an Administrator User changes an associated Administrator User or Clinical Resource Contact to an Inactive status, a Confirm Status Change message appears, but does not appear when DEX automatically inactivates a pending Clinical Resource Contact's account after 30 days.

The Confirm Status Change message prompts the Administrator User, who confirms inactivation of the associated Administrator User or Clinical Resource Contact's profile by selecting Yes, to go to the Contact Information page within My Organization to replace the inactivated Administrator User or Clinical Resource Contact with another name in the

Change To dropdown list. A similar dropdown list appears for a Clinical Resource Contact if that person's profile is inactivated.

When a User Profile Lists Credentials

A Clinical Resource Contact must have credentials, for example Genetic Counselor. That information appears on the Contact Information page for the organization.

ABOUT PERMISSIONS

Permissions refer to user security that is designed to ensure that access to data within DEX™ Diagnostics Exchange is controlled, and that only authorized users can perform activities that are assigned to them. The roles of lab administrator and lab user will be used below to illustrate permissions.

Permissions for lab users are assigned by a user who has been assigned the role of lab administrator. Within that role, the lab administrator has permission to perform the "Manage your Users" activity (among a list of other activities that correspond to that role). The lab administrator assigns one role to each lab user when creating or editing a lab user's account. Similarly, the lab user role corresponds to a list of activities that the lab user has permission to perform. To further illustrate:

- **Role —** Lab User
- **Activities —**
- Browse DEX catalog
- Browse DEX Z-Code™ identifiers
- **Role —** Lab Administrator
- **Activities —**
- Browse DEX catalog
- Browse DEX Z-Code™ identifiers
- Edit lab tests
- Maintain your account
- Manage Coverage Determination requests
- Manage your users
- Update organizational & display settings
- Manage your Test Assessments workflow

Users can view their assigned role and associated activities from the My Account window. They can open this window by clicking on My Account from the top right of any DEX window.

To change a User's role, go to My Diagnostics Exchange> Users Tab. Chapter 10 Reports Overview for Laboratories

CHAPTER 9 REPORTING FOR LAB

At this time, DEX does not offer reports for Manufacturers.

MY OFFERED TESTS REPORT

The My Offered Tests Report allows performing labs to view and print a list of the tests that they offer to give to labs with whom they are sharing information.

To generate a My Offered Tests Report:

1. From the Reports menu, select the My Offered Tests report from the Select Report Type dropdown.
2. Click the Download button, and then Open, Save, or Cancel the pdf.

COVERAGE REPORT (LABS)

The Coverage Report by Payer allows a lab to view and export the coverage decisions for their lab tests by plan type for a specific payer with whom the lab is participating. Each row of the report displays a specific lab test, the test's identifiers, and the coverage (if any) for each specific plan type for the selected payer.

To generate a Coverage Report by Payer:

1. Select My Diagnostics Exchange > Reports tab; or, from the Lab Dashboard, select the Download Coverage Report button.

   The Reports tab appears with the Coverage Report value populated in the Select Report Type field.
2. Select a payer from the Payer dropdown. The Payer dropdown is populated with active commercial payers that participate with the user's lab.

   The Download button is enabled. If the lab has run the report before for the selected payer, informational text appears with the date for the previous run.
3. Click the Download button.

   The report appears in a .csv format, allowing users to save data in a table format for sorting and evaluation purposes.

   The report header includes the name of the selected payer and the date that the report ran. The columns on the report are as follows:

   - **Test ID** — Identification number for the lab test.
   - **Test Title** — The name of the lab test.
   - **DEX Z-Code™** — The Z-Code for the lab test.

- **CPT Code —** The CPT code number or numbers and the number of units for the lab test.
- **Changed Since (date) —** The date that this report last ran for the selected payer. The current date appears if this is the first time the report has run for this payer.
- **Plan Types —** All plan types, such as HMO and Medicare, for the selected payer display even if only one plan type has coverage applied. Coverage decisions include Covered, Limited, and Not Covered.

MY SHARING CLIENT LABS

The My Sharing Client Labs Report allows performing labs to print a list of the client labs with whom they are currently sharing information.

To generate a My Sharing Client Labs report:

1. From the Reports menu, select the My Sharing Client Labs report from the Select Report Type dropdown.
2. Click the Download button, and then Open, Save, or Cancel the *.csv file.

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