

DEX ADMINISTRATOR FAQs

Lab and Manufacturer Administrator user roles, please review the frequently asked questions under the topics below to learn more about features within the DEX Diagnostics Exchange Registry.

TOPICS:

- 1. <u>MY ORGANIZATION</u>
- **2.** <u>USERS</u>
- 3. LAB TESTS AND DEX Z-CODE®
- 4. "ADD TEST" GENERAL INFORMATION
 - 4.1. DATA ENTRY
 - 4.2. TEST STATUS
- 5. "SHARING" GENERAL INFORMATION
 - 5.1. FOR REFERENCE LABS & MANUFACTURERS
 - 5.2. FOR CLIENT LABS

SECTION 1: MY ORGANIZATION

1. How can I manage my Organization's settings?

Select your name in the top right navigation bar to find the My Organization link. The My Organization allows users with the Administrator role to manage their organization including contact information, Sharing requests, test privacy settings, and payer participation.

2. How do I update the Administrator or Clinical Resource on the Contact Info tab?

Before you update the Contact Info tab, you need to set up your user.

To add a new user, you will need to navigate to: My Diagnostics Exchange > Users > Add User Record (see the Users section for more information on user roles).

Once the user is activated, you will be able to update the Contact Info tab in My Organization in the dropdown menu.

3. How can I add payers to my participation list?

Administrators may add payers by navigating to My Organization > Participation. You can select any to add to your list.

To discontinue participation with a payer, please contact DEX Customer Service at <u>DEX.Customer.Service@PalmettoGBA.com</u>.

4. How many people can have access to our Organization account?

Each Organization may have a maximum of two (2) individuals on their account.

SECTION 2: USERS

- 1. What is the difference between a Lab User and a Lab Administrator?
 - A Lab or Manufacturer User can browse the Catalog and DEX Z-Codes[®]. They cannot add tests or manage the Organization's account information and Sharing requests.
 - A Lab or Manufacturer Administrator can browse the Catalog and DEX Z-Codes. They have full permission to add/edit lab tests and manage the Organization's information—including users and Sharing requests.
- 2. Will colleagues within my Organization who register as Public Users be able to view DEX Z-Codes?

No, Public Users of the DEX Registry will not have access to DEX Z-Codes.

However, Public Users are separate from Lab or Manufacturer Users/Administrators and do not count towards the Organization's user limit of two (2).

3. How do I add a Lab User or Lab Administrator?

Go to My Diagnostics Exchange > Users > Add User Record

- Choose a role (see #1 for role definitions)
- Identify credentials (when applicable)
- Complete the remainder of the form
- Select the Save and Send Welcome Email button

4. How do I make a user Inactive?

Go to My Diagnostics Exchange > Users > click on Edit for that user > select Inactive from the dropdown menu and then Save.

5. Can I inactivate my own user record?

No, users cannot inactivate their own user records. To inactivate your record, contact another administrator for your organization or contact DEX Customer Service at <u>DEX.Customer.Service@PalmettoGBA.com</u>.

SECTION 3: LAB TESTS AND DEX Z-CODE®

1. How do I know if my test requires a DEX Z-Code?

If the test uses a CPT[®] Code within scope for the payers with which you participate, a DEX Z-Code is required for the test.

2. How do I obtain a DEX Z-Code if I am not the performing lab (e.g., if I send tests to a reference lab)?

You will need to **Request Sharing** with the performing lab in the DEX Registry to obtain their DEX Z-Code. You do not need to submit the test, but you do need to register with the DEX Registry.

Sharing is a feature within the DEX Registry that allows a client lab to obtain DEX Z-Codes for the tests sent out to reference labs. See <u>section 5</u> on Sharing of this FAQ for more information.

3. How do I obtain a DEX Z-Code for a FDA-approved/cleared test my lab is performing?

The Z-Code can be obtained through the **Sharing** functionality in DEX if the following conditions are met:

- The test is within scope of the program. Program scope can be viewed at the <u>DEX</u> <u>Program Overview</u> page.
- The test performed is FDA approved/cleared and unmodified. **Note:** If the test is being used in ways not consistent with its intended use labeling, then Sharing cannot be used.
- The manufacturer of the test has registered in DEX and received a Z-Code for the test.

If these conditions are met, then to obtain the Z-Code, you can **Request Sharing** with the manufacturer in the DEX Registry. Once the Sharing request is approved, you will have access to view the Z-Code for the test and you do not need to submit the test yourself **unless it has been modified from its intended-use labeling**. See <u>section 5</u> on Sharing of this FAQ for more information.

If the manufacturer has not registered or added the test and therefore you are unable to use the sharing function, then your organization may need to add the test. Contact DEX Customer Service for assistance.

4. Where do I go to view and manage the tests for My Organization?

Go to My Diagnostics Exchange > Lab Tests. You can use the search field, or the filter status drop down menu to find specific tests. On this tab, you may also Add Tests and Edit existing tests.

5. How do I discontinue a test that our lab no longer offers?

- To retire a test, go to My Diagnostics Exchange > select the lab test > click Edit > navigate to Effective Dates > set the End Date field to inactivate the test > click Submit.
- Retired tests will appear as Inactive.

SECTION 4: "ADD TEST" GENERAL INFORMATION

1. Where do I begin when adding a test for a Z-Code[®]?

- a. First, gather all the required information. Use the Add Lab Test Worksheet provided in
 ① Help or the 'this worksheet' link on the Catalog main page, under How to Get Started.
 - This worksheet provides an explanation of each Add Test field and allows all information to be gathered in a document before beginning data entry in the DEX Registry.
 - Tests should be entered as individual **orderable** tests and/or panels, as they are available in your lab's test directory to ordering providers.
 - We **strongly** advise labs submitting tests to the DEX Registry to have a user with clinical credentials that is familiar with molecular testing.
- b. Once all information is gathered, Select the Add Test button and fill in all required fields.
 - If you are unable to complete the submission in one sitting, use **Save as Draft** to save your progress and return to data entry later.
 - Select Review and Submit to submit the test for review.
- c. Once complete and submitted, your test will change to the In Review status for the DEX Registry team to process.
- d. When review is complete, you will receive email notification with your assigned DEX Z-Code.
- e. In some cases, you will also be notified to submit additional Technical Assessment documentation for further review. Follow the instructions in the email to locate the required forms.

2. How long does it take to receive my DEX Z-Code?

The DEX Z-Code assignment can take several weeks once submitted. If during this time you need to add something to your test or have any questions, contact us at <u>DEX.Customer.Service@PalmettoGBA.com</u>.

3. Will I receive any communication when my test is In Review status?

The DEX team reviews each submission to ensure thorough, accurate information is provided. If we have questions, we will email the Administrator(s) and/or Clinical Resource on your account from the <u>DEX.Customer.Service@PalmettoGBA.com</u> email address.

It is important that the Administrators on your account **read the emails** sent about tests submitted in the DEX Diagnostics Exchange Registry.



4. What if I have questions about using Add Test?

In addition to the Add Lab Test Worksheet, the fields in Add Test have **tooltips** that users can hover over for additional information regarding each field. Look for this icon:

For further information, access the **Help** documentation by clicking the link on the top right corner of any page in the DEX Registry.

If you need help that is not listed in these places, contact us at DEX.Customer.Service@PalmettoGBA.com.

SECTION 4.1: DATA ENTRY

1. What information should be included in the Molecular Component/Analyte field?

Provide the gene(s), chromosomes, and/or molecular component analyzed for the associated test/assay. Use italics and HGNC-approved gene symbols (e.g., *FLT3*, *IDH1*, *IDH2*).

For infectious disease testing: list all organisms and antimicrobial resistance genes (e.g., *mecA* for methicillin resistance) targeted by the assay. Use italics for non-viral organism names (e.g. *Escherichia coli*).

2. I received the error message about exceeding 4000 characters when I entered my data in the Molecular Component/Analyte field, how can I proceed?

Be sure to include only HGNC-approved gene symbols and remove any extra information (e.g., reference sequence numbers or gene chromosomal location).

- If the information exceeds the character limit, you may use the Contributing Components fields to complete the data entry.
- If you cannot complete the full list, you may enter the total number of genes (e.g., "200 genes").

Also, it is possible that some extra characters are "hidden" in your data entry.

- When copying and pasting from a PDF or rich text editor, additional spaces and/or hidden characters may be included. Please verify that no extra spaces/characters have been included as these will count towards the character limit.
- Additionally, tables cannot be pasted into DEX Registry fields; please paste these into another document and remove the formatting prior to pasting into DEX.

3. What information should I put in the Device/Kit Name field?

The Device/Kit Name should indicate the full commercial instrument and kit name provided by the manufacturer. Please refrain from using abbreviations.

4. If my lab performs an FDA cleared/approved test, do I need to add the FDA information to the DEX Diagnostics Exchange Registry?

Yes, if your lab is performing an FDA 510(k) cleared/PMA test, the FDA Document # and Device/Kit fields are required. Any modifications to FDA cleared/approved protocols will need to be indicated and details of the modification provided in the Contributing Components field.

5. What if the Category entry I need is not listed?

If a Category entry is not listed, enter a suggestion by clicking the **Add a Suggestion** link and submit it for review.

6. How do I enter a CPT[®] Code?

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Start by typing the desired code into the Add CPT® Codes (Current) field:

Add a new Test		
General 🔮	Financial Add CPT® Code	es (Current) * 🕜
Categories 🔮	0147]	
Financial	CODE 🔺	DESCRIPTION
Advanced	81470	X-LINKED INTELLECTUAL DBLT
	81471	X-LINKED INTELLECTUAL DBLT
	81479	UNLISTED MOLECULAR PATHOLOGY
	88147	CYTOPATH C/V AUTOMATED
	CPT® CODES	CURRENT) UNITS DESCRIPTION REMOVE

When the grid appears, **click** on the desired CPT[®] Code to select it, and enter the number of units in the window that appears:

Add a new Test		
	Financial	
General 🛛 🔮		
	Add CPT [®] Code	les (Current) * 🕐
Clinical	8147	
Categories 🛛 🗸		
Financial	CODE *	DESCRIPTION
Advanced	81470	X-LINKED INTELLECTUAL DBLT
/ aranood	81471	X-LINKED INTELLECTUAL DBLT
+	81479	UNLISTED MOLECULAR PATHOLOGY
	88147	CYTOPATH C/V AUTOMATED
	CPT® CODES	S (CURRENT) UNITS DESCRIPTION REMOVE

How to enter a CPT[®] code, continued.

Note: clicking the Add button without entering units will default to one (1) unit:

CPT Units
Please enter the number of units
+
Cancel AD

Completed CPT[®] Code:

Add a new Test					
		Financial			
General	9	_			
Clinical	✓ ¹	Add CPT® Codes (Current) * 👔			
Categories	9				
Financial	ໍົ	CPT [®] CODES (CURRENT)		DESCRIPTION	REMOVE
Advanced		81479	1	UNLISTED MOLECULAR PATHO	Remove
	C				

7. What are the MoIDX[®] and DEX Recommended CPT[®] Codes?

The MoIDX Recommended CPT[®] Code is the code that has been specified by the MoIDX Program (administered by Palmetto GBA) to be used in conjunction with your assigned DEX Z-Code[®] on claims to your MAC, if they are participating in the MoIDX Program.

Similarly, the DEX Recommended CPT[®] Code is the code assigned to be used in conjunction with your DEX Z-Code on claims to other payers participating in the DEX Registry.

When your test is updated with a Recommended CPT[®] Code, you will be notified via email. These fields cannot be modified by the Lab Administrator.

Note: The Recommended CPT® Code may differ from that which was entered in the CPT® Code (Current) field.

SECTION 4.2: TEST STATUS

1. What do the different statuses mean for my lab test?

Throughout the DEX Z-Code[®] assignment process, test status will change from **Draft** to **In Review, Inactive**, and then **Active**. Once a test becomes Active you will have access to the assigned DEX Z-Code and the test will appear in the Catalog. Active tests may be edited if/when updates are needed so long as a Technical Assessment is not in progress for the test.

2. Why did my test return to Draft status after I submitted it?

If the DEX Registry team requires clarification on your test submission, we will email you and return the test back into **Draft** status. While your test is in Draft status, you will be able to make any necessary edits and **resubmit** to continue the review process.

3. Why does my test show as Inactive?

A test will appear as **Inactive** for a short period of time prior to becoming Active with a DEX Z-Code.

4. Once I add my tests to the DEX Diagnostics Exchange Registry, where can I find them to review their status?

To view your tests in the DEX Registry, go to My Diagnostics Exchange Registry and select the Lab Tests tab. This will provide an overview of your tests entered in the DEX Registry and their statuses.

NOTE: Your test will temporarily appear as **Inactive** prior to becoming Active with a DEX Z-Code.



SECTION 5: "SHARING" GENERAL INFORMATION

1. What is the Sharing feature?

Sharing is a feature within the DEX Diagnostics Exchange Registry that allows a client lab to see their **reference laboratory** test details, including DEX Z-Code[®] identifiers and CPT[®] codes to be used for billing. You can then place the DEX Z-Code, obtained through Sharing, on the claims submitted to the payers. If you are using a reference lab for a test, you do not have to add the test and submit for a DEX Z-Code yourself.

Sharing can also be used to obtain DEX Z-Codes and CPT[®] codes from **Manufacturers** with FDA-cleared/approved tests in the DEX Registry. **This allows the client lab who is performing a unmodified test to obtain the Z-Code without adding the test themselves.** This is only applicable if the performing lab is using the test within the intended-use labeling (i.e., it is unmodified) and the Manufacturer has obtained a Z-Code for their test.

NOTE: If the performing lab has modified the test in any way they will need to add the test themselves for their own Z-Code.

SECTION 5.1: "SHARING" FOR REFERENCE LABS & MANUFACTURERS

1. How does my Organization know if another laboratory requested Sharing?

You will receive email notification from DEX customer service. Additionally, an orange indicator will appear near My Organization link in the top right navigation bar when requests are pending as well as the Sharing tab as seen below.

	a. DEX™ □ DIAGNOSTICS EXCHANGE		🛠 Lab Sage 🗸 📿 Contact Us	🚹 Help
Catalog	My Diagnostics Exchange	Determination Requests Bessage Center	er g 😵 My Organization	
Catalog Ove	rview		Logout	

Edit Organization					×
Sage Clinical, Inc.					
GENERAL INFO CONTACT IN FO 🚯 SHARING T	EST PRIVACY P	ARTICIPATION	CPT CODEBRIDGE™	ACTIVITY LOG	_

2. How do I manage incoming sharing requests?

- Log in to the DEX Registry
- Go to My Organization (click your name in the top right navigation bar to access this)
- Select the Sharing tab
- Review the name of requesting lab
 - o If you have a client/billing relationship, select Approve
 - o If you do not have a client/billing relationship, select **Do Not Approve**

	Share Requests						
1	INCOMING REQUESTS O	UTGOING REQUESTS					
	Filter status:						
	ACTIONS	STATUS	NAME	сіту	STATE	DATE & TIME	
	Approve Do Not Approve	Pending	Extreme Genetics Lab	Arlington	VA	04/28/2021 07:42 AM	
11		Approved	Cheyenne Regional Medical C	CHEYENNE	WY	04/16/2021 08:47 AM	
		Approved 9	Z-Code Diagnostics	Anywhere	CA	10/26/2017 01:03 PM	
	Allow Sharing	Not Approved	Quad Cities Clinical Laborator	Ioline	IL	10/26/2017 12:35 PM	
	Items: 1 - 4 Total: 4 Items Per Page: 10 · First & Back Page 1 of 1 Next >> Last If you would like to discontinue sharing with one or more labs, please send an email to Customer Service.						
						Cancel SAVE	

3. Once the Sharing Request is approved, how does this affect the privacy of my test information?

The DEX Z-Code[®], CPT[®] Code, and Methodology will become visible, but all other fields marked private will remain private. To review privacy settings, go to the My Organization > Test Privacy tab.

5. As a Reference Laboratory, is there a way to provide our DEX Z-Codes to client labs that are registered in the DEX Diagnostics Exchange Registry and/or our internal billing staff?

You can print a list of tests and/or create a secure PDF document to distribute to client laboratories with which Sharing has been approved within the DEX Registry and your internal billing team.

- Click on your name in the top right navigation bar
- Click on the My Organization link
- Click the Sharing tab
- Click Download Report of All Offered Tests

NOTE: Reports that include DEX Z-Codes should NOT be available publicly.

6. May I include the DEX Z-Codes on my website?

No, DEX Z-Codes may not to be added to any laboratory or manufacturer websites, test directories, invoices, marketing, and/or published materials. For additional information please review the full DEX Z-Code Terms & Conditions by selecting your name in the top right navigation bar, selecting My Organization, viewing the **Z-Code Identifier Term & Conditions** table at the bottom of the General tab, then selecting the most recent version number.

7. Can I choose to discontinue Sharing with a client laboratory?

To make any changes to your existing Sharing relationships, you must contact Customer Service at <u>DEX.Customer.Service@PalmettoGBA.com</u>.

8. As a Manufacturer, what are the Discrete Sharing and Global Sharing options?

With Discrete Sharing, the incoming sharing requests from labs must be manually approved. The application defaults to Discrete Sharing and we encourage the use of Discrete Sharing to maintain control over who is accessing your proprietary information (i.e., Z-Codes).

Manufacturers also have the option to enable Global Sharing. If Global Sharing is selected, then the incoming requests will automatically be approved. This option is available for manufacturers who expect large numbers of incoming sharing requests for their tests due to having numerous client labs.



Discrete and Global Sharing, continued.

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Go to My Organization by clicking your name in the top right navigation bar then click on the Sharing tab for the Client Lab Sharing options.

Edit Organization								
Corporation								
GENERAL INFO CONTACT INFO SHARING TEST PRIVACY PAI	RTICIPATION ACTIVITY LOG							
	Frequently Asked Questions							
Client Lab Sharing								
Discrete Sharing Approve information sharing with Client Labs on a case-by-case basis.								
Global Sharing Approve information sharing with all Client Labs.	Download Report of All Offered Tests							



SECTION 5.2: "SHARING" FOR CLIENT LABS

1. How do I make a Sharing Request?

Once your Organization is registered and your account is active:

- Select the Labs & Manufacturers Catalog
- Search for any of your reference labs or manufacturers who market the tests you perform
 - o Click on that name link OR
 - Select the "+" sign to expand a parent organization's individual facilities, find the facility you send the specimen for processing (or testing)
- Select **Request Sharing** button at the top right corner.
- Once your reference lab/manufacturer approves your Sharing Request, find the DEX Z-Code[®] by searching the Lab Tests Catalog using the lab test code or name. See #3 for more information.

2. How do I check if my Sharing Request has been approved?

Go to My Organization by clicking your name in the top right navigation bar then click on Sharing tab to view the Status of incoming or outgoing requests. Select outgoing requests and view the status of the request.

Filter status:		¬			
All Statuses	~				
STATUS		NAME	CITY	STATE	DATE & TIME
Not Approved	Ð	Hankins Lab	Malvern	PA	04/16/2021 08:51 AM
Approved	Ð	Cheyenne Regional Medical Center	CHEYENNE	WY	04/16/2021 08:50 AM
Pending	Ð	Lab of America	Billings	MT	04/16/2021 08:48 AM
Pending	Ð	Wesson Laboratories	Nashville	TN	10/26/2017 02:39 PM
Approved	Ð	Quad Cities Clinical Laboratory	Moline	IL	10/26/2017 02:38 PM
Approved	Ð	Z-Code Diagnostics	Anywhere	CA	10/26/2017 02:23 PM
Approved	Ð	ARUP	Madison	NJ	10/26/2017 01:02 PM
Items: 1 - 7 Total:	7 Item	is Per Page: 10 🗸	Fir	st « Back	Page 1 of 1 Next » Last

How to view Sharing approval(s), continued.

Alternatively, an icon will also appear in the Labs & Manufacturers Catalog indicating laboratories that have requests pending, approved, or not approved. The definition of each icon can be seen below in the Sharing legend on the left-hand side of the screen.

PALMETTO GBA: DEXTM + CLONEN GOLD + COMPANY DIAGNOSTICS EXCHAN	IGE		🛞 Lab Sage 🗸 🛛 🔎 Contact U	Js 🚹 Help				
Catalog My Diagnostics Exchange Determination Requests Message Center								
Catalog Overview All Labs & Manufacturers FAQ								
Choose a Catalog: Labs & Manufacturers V Search Start typing to search Labs & Manufacturers CLEAR								
✓ Approved	TITLE	ADDRESS	CITY	STATE				
	Another OHIO Test Lab	123 Main Street	Maumee	ОН				
	ARUP 🗸 🕂	3 Gi alda Farms	Madison	NJ				
Not Approved	Cheyenne Regional Medical Center	214 E 23RD ST	CHEYENNE	WY				
	Cowboys Nation	1 Co <mark>v</mark> boy Lane	Dallas	TX				
	Extreme Genetics Lab	847 McIntyre Road	Arlington	VA				
	Hankins Lab 9	Mair Street	Malvern	PA				
	Independent Health Test Lab	123 Test Street	Test	MA				
	Lab of America	655 Elm St.	Billings	MT				
	Lab Tests International	123 Main Street	Broomfield	со				
N	LabCorp Birmingham	123 Main St	Birmingham	AL				

3. How do I find the DEX Z-Code[®] once the Sharing Request has been approved?

From the DEX Catalog Overview, there are 2 ways to search for the DEX Z-Code:

- Select the Lab Tests Catalog. You may search by keyword (e.g., Test ID, Test Name) to find the specific test. You may choose to search for both the Lab Name and Test ID separated by a space in the Search field. Once you see the test in the search results, select the Test Name to view the Test Details page. You will find the DEX Z-Code on the Test Details page.
- Select the Labs & Manufacturers Catalog. Search for your reference lab or manufacturer name. Select the lab to view full menu. Once you locate the specific test, you may select the Test Name to view the Test Details page. You will find the DEX Z-Code on the Test Details page.

4. Can I search for a reference lab's DEX Z-Code using the CPT[®] code?

No, at this time you cannot search the Catalog by CPT[®] Code – see #3 for the best ways to search for lab tests and DEX Z-Codes.

5. If I cannot find the reference lab/manufacturer or the test listed in the DEX Registry, what should I do?

Please contact your reference lab to let them know of your need for DEX Z-Code identifiers.

If the manufacturer has not registered or added the test and therefore you are unable to use the Sharing function, then your organization may need to add the test.

If your reference lab is not responsive, or your manufacturer is not in the DEX Registry, please feel free to contact Customer Service at <u>DEX.Customer.Service@PalmettoGBA.com</u>.

6. What if my reference lab sends out to another lab?

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You will need to request Sharing with the lab that **performs** the test to obtain the DEX Z-Code[®]. If the request is not approved, contact Customer Service at <u>DEX.Customer.Service@PalmettoGBA.com</u>