



ADD TEST FAQ

Add Test workflow allows Laboratory and Manufacturer Administrators to enter lab test information for obtaining a DEX Z-Code™ identifier. Lab Tests include required fields that must be completed to proceed through the application process. Below is a list of frequently asked questions to help guide you through the process of adding a test.

TOPICS:

- **SECTION 1: GENERAL INFORMATION**
- **SECTION 2: DATA ENTRY**
- **SECTION 3: TEST STATUS**

SECTION 1: GENERAL INFORMATION

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

- If the test has a CPT® Code(s) within scope for the payers with which you participate
- Tests should be entered as individual orderable tests and/or panels

2. How do I obtain a DEX Z-Code if I am not the performing lab?

You will need to Request Sharing with the performing lab in DEX to obtain their DEX Z-Code. You do not need to submit a separate test. Please see the Sharing FAQ for details.

3. Where do I begin when adding a test for a Z-Code?

- First, gather all the required information (see the Download Worksheet Excel spreadsheet link below the Add Test button that provides an explanation of each field in Add Test).
- We strongly advise labs submitting tests to DEX to have a user with clinical credentials that is familiar with molecular testing.
- Next, Select the Add Test action button and fill in all required fields.
- Once complete and submitted for review, your test will go 'In Review' status for the DEX team to process.
- When complete, you will receive email notification with your assigned DEX Z-Code.
- In some cases, you will be notified to submit additional Technical Assessment documentation for further review.



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

The DEX Z-Code assignment process can take several weeks.

5. 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 and/or Clinical Resource on your account listed in the DEX™ Diagnostics Exchange.

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

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

A worksheet is available by clicking the Download Worksheet link below the Add Test button that provides an explanation of each field in Add Test.

In addition, the forms in Add Test have tooltips that users can hover over for additional information regarding each field.



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



SECTION 2: DATA ENTRY

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

- For MDx tests, provide the gene(s), chromosomes, and/or any molecular component analyzed for the associated test/assay. Use HGNC approved gene nomenclature and italics to indicate gene symbols.
- For Non-MDx tests, provide the pathogen, protein or substance being tested. Use italics for non-viral organism names (e.g., *E.coli*).

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

- Be sure to include only gene names, remove any extra information, for example, reference sequence numbers or the gene chromosomal location.
- If the information exceeds the character limit, use the contributing components fields to complete the data entry.
- If you cannot complete the full list, enter the total number of genes, for f



- Also, it is possible that some extra characters are hidden in your data entry, for example, when copying and pasting from Word or another Rich Text Editor, additional spaces and/or hidden characters may be included. Please verify that no extra characters have been included.

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

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

4. If my lab performs an FDA 510(k)/PMA test, do I need to add it to the DEX Diagnostics Exchange to obtain a DEX Z-Code?

YES, you need to add the test to obtain a DEX Z-Code for FDA 510(k)/PMA devices. You will need to provide the FDA document number(s) and select if there are modifications to the protocols.

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?

Start by entering a current CPT[®] Code, typing the desired code into the box.

The screenshot shows the 'Add a new Test' window with the 'Financial' category selected. The 'Add CPT[®] Codes (Current)' field contains '8147' and is highlighted with a red arrow. Below it is a table of CPT codes for selection.

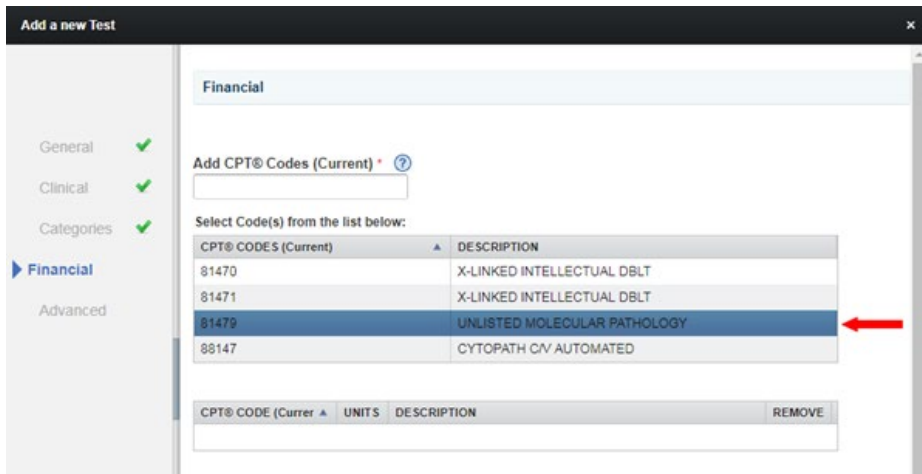
CPT [®] CODES (Current)	DESCRIPTION
81470	X-LINKED INTELLECTUAL DBLT
81471	X-LINKED INTELLECTUAL DBLT
81479	UNLISTED MOLECULAR PATHOLOGY
88147	CYTOPATH C/V AUTOMATED

Below the table is a summary table with columns: CPT[®] CODE (Currer), UNITS, DESCRIPTION, and REMOVE.

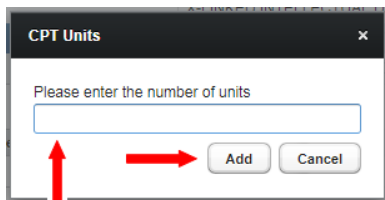


How to enter a CPT® Code, continued

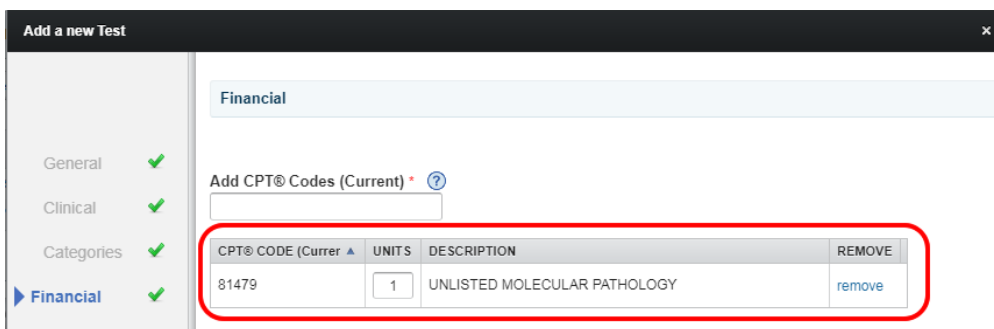
When the grid appears, click on the desired CPT® code to select it, and enter the number of units in the window that appears.



Clicking the Add button without entering units will default to one (1) unit.



Completed CPT® Code



7. What is the MoIDX Recommended CPT® Code?

The MoIDX Recommended CPT® code is the code that has been specified by the Palmetto GBA MoIDX program to be used in conjunction with your assigned Z-Code on claims to your MAC. If your test is updated with a MoIDX Recommended CPT® code, you will be notified via email. This field cannot be modified by the laboratory administrative user.



NOTE: The MolDX recommended CPT® code may differ from that which was entered in the CPT® Code (Current) field.

SECTION 3: TEST STATUS

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

Throughout the DEX Z-Code assignment process, test status will change from Draft, In Review, to Inactive, to Active. Once a test becomes Active, the you will have access to the DEX Z-Code, may edit the test—when needed, and the test will appear in the Catalog.

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

If the DEX 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?

Your 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, where can I find them to review their status?

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

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