

The screenshot shows the CMS.gov website interface. At the top, there is a navigation bar with links for Home, About CMS, Newsroom, FAQs, Archive, Share, Help, and Print. Below this is a search bar with the text 'Learn about your healthcare options' and a 'Search' button. A horizontal menu contains several categories: Medicare, Medicaid/CHIP, Medicare-Medicaid Coordination, Private Insurance, Innovation Center, Regulations & Guidance (highlighted in blue), Research, Statistics, Data & Systems, and Outreach & Education. The main content area is titled 'Clinical Laboratory Improvement Amendments (CLIA)'. A green callout box with white text reads: 'This tutorial of the CMS.gov website Clinical Laboratory Improvement Amendments (CLIA) page will demonstrate how to determine if a Current Procedural Terminology CPT® code requires the QW modifier. To begin, click: Categorization of Tests'. In the left-hand navigation pane, the link 'Categorization of Tests' is highlighted with a red box and a yellow arrow. Below the callout, the page content includes a list of links for 'How to Apply for a CLIA Certificate, Including International Laboratories', 'State Agency & Regional Office CLIA Contacts', 'Accreditation Organizations/Exempt States', 'Certificate of Waiver Laboratory Project', 'Certification Boards for Laboratory Directors of High Complexity Testing', and 'CLIA Brochures'. A list of bullet points provides additional information about laboratory contacts, CMS authority, and research testing.

This tutorial of the CMS.gov website Clinical Laboratory Improvement Amendments (CLIA) page will demonstrate how to determine if a Current Procedural Terminology CPT® code requires the QW modifier.

To begin, click: Categorization of Tests

Clinical Laboratory Improvement Amendments (CLIA)

- [How to Apply for a CLIA Certificate, Including International Laboratories](#)
- [State Agency & Regional Office CLIA Contacts](#)
- [Accreditation Organizations/Exempt States](#)
- Categorization of Tests**
- [Testing](#)
- [CLIA Brochures](#)
- [CLIA Regulations and Federal Register Documents](#)
- [CLIA Related Hearing Decisions and Compliance Topics](#)
- [CLIA Statistical Tables/Graphs](#)
- [CME Courses for Laboratory Directors of Moderate Complexity Laboratories](#)
- [Cytology Proficiency Testing](#)
- [Individualized Quality Control Plan](#)

Categorization of Tests

Since November 13, 2003, the Food and Drug Administration (FDA) has had the authority to implement the Clinical Laboratory Improvement Amendments (CLIA) test complexity categorization provisions, which includes, but is not limited to the following:

- Interpreting the CLIA provisions related to complexity categorization;
- Holding public workshops and meetings on CLIA complexity categorization; and,
- Developing and issuing implementing rules and guidance for CLIA complexity categorization.

Refer to the link below to access the FDA CLIA database containing the commercially marketed in vitro test systems categorized by the FDA since January 31, 2000 and the tests categorized by the Centers for Disease Control and

At the bottom of the **Categorization of Tests** page, select:

List of Waived Tests

- A list of tests (CPT-4 and HCPCS codes) subject to CLIA edits that includes non-waived and non-PPMP tests;
- A list of laboratory certification (LC) codes [CLIA specialty and subspecialty information] that is for information purposes only; and
- A list of tests (CPT-4 codes) excluded from CLIA edits within the 80000 series.

Downloads

- [List of Waived Tests \[PDF, 1MB\]](#)
- [List of PPMP \[PDF, 9KB\]](#)
- [Tests Subject to CLIA Edits \[PDF, 282KB\]](#)
- [LC Codes \[PDF, 15KB\]](#)
- [Tests \(CPT-4\) Excluded From CLIA Edits \[PDF, 93KB\]](#)

At the bottom of the **Categorization of Tests** page, select: List of Waived Tests

TESTS GRANTED WAIVED STATUS UNDER CLIA			
<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
81002	Dipstick or tablet reagent urinalysis – non-automated for bilirubin, glucose, hemoglobin, pH, urobilinogen, and uro	Various	Screening of urine to monitor/diagnose various diseases, diabetes, the state of the kidney or urinary tract, and
<p>As you can see, CPT® code 82270 does not require the QW modifier.</p> <p>Click CPT® code 82270 to continue.</p>			
81025	Urine pregnancy tests by visual color comparison	Various	Diagnosis of pregnancy
82270	Fecal occult blood	Various Click Box	Detection of blood in feces from whatever cause, blood (colorectal cancer screening)
82962	Blood glucose by glucose monitoring	Various	Monitoring of blood glucose levels
<p>For this demonstration, we will use two common CPT® codes:</p> <p>82270 - Fecal occult blood</p> <p>80061 - Jant Pharmacal LipidPlus Lipid Profile and Glucose Measuring System</p>			
83026			level in blood
84830	comparison for human luteinizing hormone		(optimal for conception)
85013	Blood count; spun microhematocrit	Various	Screen for anemia

The TESTS GRANTED WAIVED STATUS UNDER CLIA pdf file opens.

As you can see, CPT® code [82270](#) does not require the QW modifier.

Click CPT® code [82270](#) to continue.

For this demonstration, we will use two common CPT® codes:

[82270](#) - Fecal occult blood

[80061](#) - Jant Pharmacal LipidPlus Lipid Profile and Glucose Measuring System

TESTS GRANTED WAIVED STATUS UNDER CLIA				
<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>	
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW	1. Abaxis, Piccolo xpress Chemistry Analyzer {Lipid Panel Reagent Disc} (Whole Blood)	Abaxis, Incorporated Click Box	Measures total cholesterol, HDL cholesterol, and triglycerides in	blood
	2. Infoclin USA LipidPro lipid profile and (LipidPlus Lipid Profile test strips)	Infoclin Co., Ltd.		
	3. JaniPro Glucose measuring System (LipidPlus Lipid Profile test strips)			
	4. Piccolo Point of Care Chemistry Analyzer (Lipid Panel Reagent Disc) (Whole Blood)	Abaxis, Incorporated		
	5. Polymer Technology Systems CardioChek PA Analyzer {PTS Panels Lipid Panel Test Strips}	Polymer Technology Systems, Inc.		
	6. Polymer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home Lipid Panel test strips)*	Polymer Technology Systems, Inc.		
	7. Polymer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels Lipid Panel test strips)	Polymer Technology Systems, Inc.		

However, CPT® code 80061 does require the QW modifier.
Click CPT® code 80061 to continue.

However, CPT® code 80061 does require the QW modifier.

Click CPT® code 80061 to continue.

The screenshot shows the CMS.gov website with a navigation bar at the top. The main content area is titled "Clinical Laboratory Improvement Amendments (CLIA)". A green tutorial box is overlaid on the page, containing the following text:

This tutorial has demonstrated how to determine if a CPT® code requires the QW modifier.

Click the button below to restart, or close this window to continue.

Refer to the CMS CLIA webpage for additional information at:

<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html>

Below the tutorial box, there is a "Restart" button and a list of links related to CLIA, including "Information about what is CMS' authority regarding Laboratory Developed Tests (LDTs) and how does it differ from FDA's authority", "CMS Blog - FDA & CMS For LDT Quality Requirements", and "Information on research testing and CLIA".

This tutorial has demonstrated how to determine if a CPT® code requires the QW modifier.

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