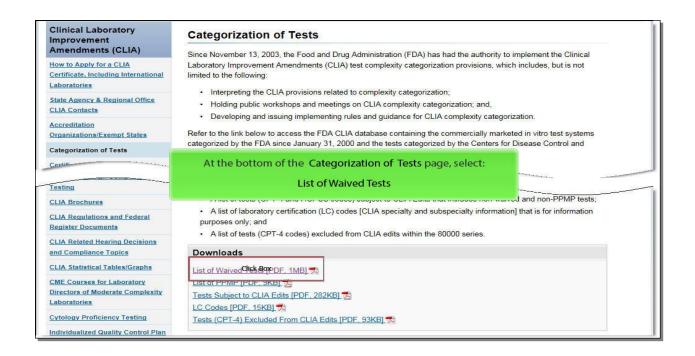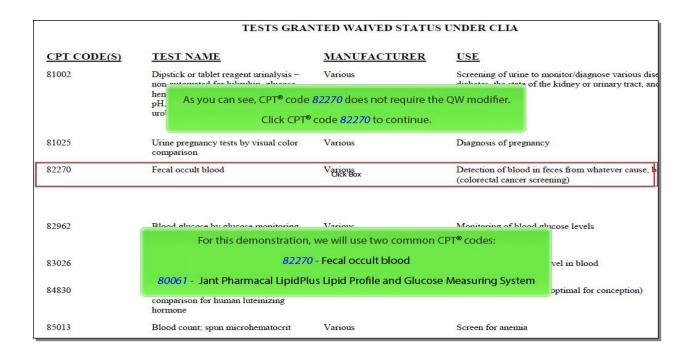This tutorial of the CMS.gov website Clinical Laboratory Improvement Amendments (CLIA) page will demonstrate how to determine if a Current Procedural Terminology CPT® code requires the QW modifier.

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

Certifi...

...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] — Click Box

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

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
81002	Dipstick or tablet reagent urinalysis – non-automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen	Various	Screening of urine to monitor/diagnose various diseases, diabetes, the state of the kidney or urinary tract, and
81025	Urine pregnancy tests by visual color comparison	Various	Diagnosis of pregnancy
82270	Fecal occult blood	Various	Detection of blood in feces from whatever cause, b (colorectal cancer screening)
82962	Blood glucose by glucose monitoring	Various	Monitoring of blood glucose levels
83026			vel in blood
84830			comparison for human luteinizing hormone	ptimal for conception)
85013	Blood count; spun microhematocrit	Various	Screen for anemia

As you can see, CPT® code *82270* does not require the QW modifier.

Click CPT® code *82270* to continue.

Click Box

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

82270 - Fecal occult blood

80061 - Jant Pharmacal LipidPlus Lipid Profile and Glucose Measuring System

---

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			
CPT CODE(S)	**TEST NAME**	**MANUFACTURER**	**USE**
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 tr[...] blood
	2. Infopia USA LipidPro lipid profile and [...] (Lip[...]	Infopia Co., Ltd.	
	3. Jant [...] Pro[...] 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. Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home Lipid Panel test strips)*	Polymer Technology Systems, Inc.	
	7. Poylmer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels Lipid Panel test	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.

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