

The screenshot shows the CMS.gov website with the following elements:

- Header: CMS.gov logo, navigation links (Home, About CMS, Newsroom, FAQs, Archive, Share, Help, Print), and a search bar.
- Navigation Menu: Medicare, Medicaid/CHIP, Medicare-Medicaid Coordination, Private Insurance, Innovation Center, Regulations & Guidance (highlighted), Research, Statistics, Data & Systems, Outreach & Education.
- Breadcrumbs: Home > Regulations and Guidance > Clinical Laboratory Improvement Amendments (CLIA) > Clinical Laboratory Improvement Amendments (CLIA)
- Left Sidebar: Clinical Laboratory Improvement Amendments (CLIA) section with links for: How to Apply for a CLIA Certificate, Including International Laboratories; State Agency & Regional Office; CLIA Contacts; Accreditation Organizations/Exempt States; Categorization of Tests (highlighted with a yellow arrow); Certificate of Waiver Laboratory Project; Certification Boards for Laboratory Directors of High Complexity Testing; CLIA Brochures.
- Main Content: Title "Clinical Laboratory Improvement Amendments (CLIA)". A green callout box contains the text: "Este tutorial de la página CLIA en el sitio Web de CMS.gov demostrará cómo determinar si un código Current Procedural Terminology CPT® requiere el modificador QW. Para comenzar, haga clic en: Categorization of Tests". Below this, there is a section "For the following information, refer to the downloads/links listed below:" followed by a bulleted list of links.

Slide 1

Text Captions: Este tutorial de la página CLIA en el sitio Web de CMS.gov demostrará cómo determinar si un código Current Procedural Terminology CPT® requiere el modificador QW.

Para comenzar, haga clic en: 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**
- [CPT-4](#)
- [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

**Al fondo de la página de Categorization of Tests, seleccione:**

**List of Waived Tests**

... of tests (CPT-4 codes) subject to CLIA edits within the 80000 series; 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 \[PDF, 3KB\]](#)
- [Tests Subject to CLIA Edits \[PDF, 282KB\]](#)
- [LC Codes \[PDF, 15KB\]](#)
- [Tests \(CPT-4\) Excluded From CLIA Edits \[PDF, 93KB\]](#)

Slide 2

Text Captions: Al fondo de la página de Categorization of Tests, seleccione:

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. Includes glucose, hemoglobin, pH, and urobilinogen.	Various	Screening of urine to monitor/diagnose various disorders of the kidney or urinary tract, and
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, (colorectal cancer screening)
82962	Blood glucose by glucose monitoring	Various	Monitoring of blood glucose levels
83026			Level in blood
84830	Comparison for human luteinizing hormone		(optimal for conception)
85013	Blood count; spun microhematocrit	Various	Screen for anemia

Slide 3

Text Captions: Como puede ver, el código CPT® 82270 no requiere el modificador QW.

Haga clic en el código CPT® 82270 para continuar.

El archivo PDF TESTS GRANTED WAIVED STATUS UNDER CLIA abre.

Para esta demostración, usaremos dos códigos CPT® comunes:

82270 - Fecal occult blood

80061 - Jant Pharmacal LipidPlus Lipid Profile and Glucose Measuring System

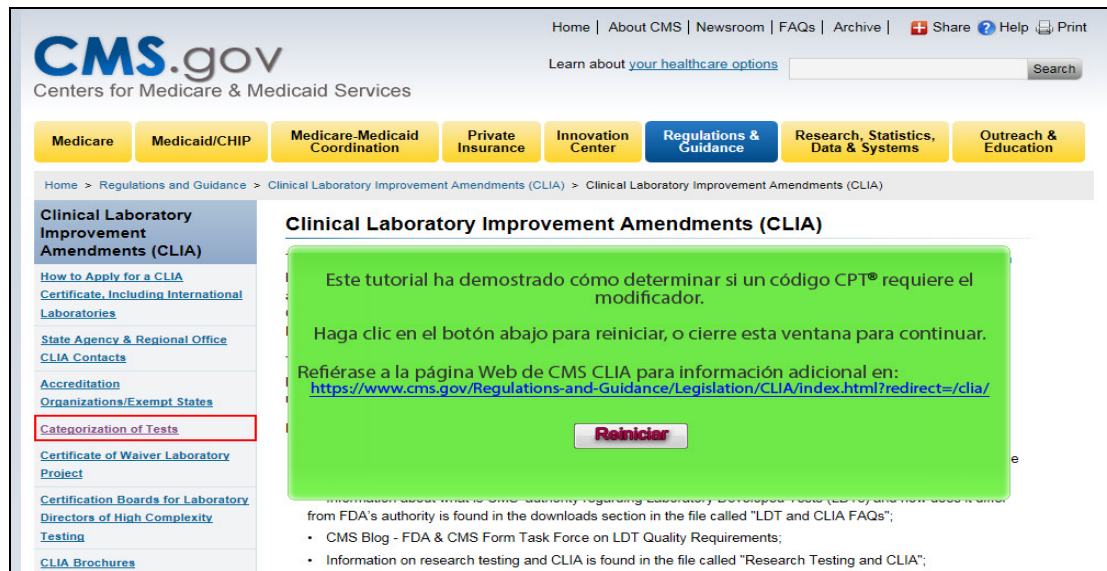
TESTS GRANTED WAIVED STATUS UNDER CLIA			
<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW	1. Abaxis, Piccolo xpress Chemistry Analyzer (Lipid Panel Reagent Disc) (Whole Blood)	Abaxis, Incorporated Click Box	Measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
	2. Infocis USA LipidPlus Lipid Profile and (LipidPlus Lipid Profile test strips)	Infocis Co., Ltd.	
	3. JaniPro 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. 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.	

Sin embargo, el código CPT® 80061 requiere el modificador QW.  
Haga clic en el código CPT® 80061 para continuar.

Slide 4

Text Captions: Sin embargo, el código CPT® 80061 requiere el modificador QW.

Haga clic en el código CPT® 80061 para continuar.



The screenshot shows the CMS.gov website with a navigation menu at the top. The main content area is titled "Clinical Laboratory Improvement Amendments (CLIA)". A green box contains the following text in Spanish:

Este tutorial ha demostrado cómo determinar si un código CPT® requiere el modificador.

Haga clic en el botón abajo para reiniciar, o cierre esta ventana para continuar.

Refiérase a la página Web de CMS CLIA para información adicional en:  
<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=clia/>

Below the text is a button labeled "Reiniciar".

Slide 5

Text Captions:

Este tutorial ha demostrado cómo determinar si un código CPT® requiere el modificador.

Haga clic en el botón abajo para reiniciar, o cierre esta ventana para continuar.

Refiérase a la página web de CMS CLIA para información adicional en:

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