

**Crosswalk for Changes to Clinical Laboratory Improvement Amendments of 1988  
(CLIA) Application for Certification (CMS-116)**

<b>Section # on current CMS-116 (07/05)</b>	<b>Type of Change</b>	<b>Rationale for Change</b>
I General Information Top left block	Add: <b>Survey</b> Modify: <b>Change in Certificate Type</b> Add: <b>Other Changes</b>	Expanded selection reasons to describe reasons for completion of CMS-116 in accordance with CLIA notification requirements in 42 CFR Part 493.
CLIA Identification Number	<del>CLIA Identification Number</del>	Removed 'identification' from label in accordance with S&C 07-16 letter (Clarification of Provider # Nomenclature)
Facility Address	<b>Bold (Physical Location of Laboratory Building, Floor, Suite if applicable.)</b> Add note: <b>Fee coupon/certificate will be mailed to this address unless mailing address is specified.</b>	Enhanced completion instructions to reduce errors in mailing CLIA fees & certificates
Mailing/Billing Address	<b>Bold: (if different from street address, include attention line and/or Building, Floor, Suite)</b>	Enhanced completion instructions to reduce errors in mailing CLIA fees & certificates
Gray area	Add: <b>For office use only:</b> <b>Date Received: _____</b>	Added field to assist in monitoring timeliness of user receipt and data entry of CMS-116 in data base.
III Type of Laboratory	Add: <b>Assisted Living Facility and Prison</b> Sort: values in alphabetical order and renumber	Added additional facility types to reflect demographics of laboratory population. Sort in alphabetical order for ease in completion.
IV Hours of Laboratory Testing	Add: (...using <b>HH:MM</b> format.)  Delete: <b>AM PM on FROM and TO lines. Delete 2 lines provided for hours</b>	Added clarifying instructions for completing sections and to facilitate data entry. Deleted extraneous lines for reporting hours of laboratory testing to reduce reporting burden on laboratory and data entry processing.
V. Multiple Sites	Add: <b>Yes</b> block. <b>If yes, complete the remainder of the section.</b> Add: <b>1 Is this a laboratory that has temporary testing sites? YES NO</b> Add: <b>2</b> (in front of existing 'not-for-profit language') Add: <b>3</b> (in front of existing 'hospital' language)	Added new question and re-ordered existing questions to conform with regulatory exceptions as specified in 42 CFR Part 493.
VI. Waived Testing	Add: <b>Check if no waived tests performed.</b>	Added instructions to assist State agency in screening CMS-116 form for completion and accuracy.

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<p>VII. <del>NONWAIVED- TESTING- PPM TESTING</del></p>	<p>Add: New Section VII called ‘<b>PPM TESTING</b>’ + <b>Indicate the estimated TOTAL ANNUAL TEST volume for all PPM tests performed</b> + <b>Check if no PPM tests performed.</b></p>	<p>Added new field to collect PPM tests to assist CMS in reporting total laboratory test volume. Added instructions to assist State agency in screening CMS-116 form for completion and accuracy.</p>
<p>VIII <del>TYPE OF CONTROL NONWAIVED TESTING</del></p>	<p>Modify: Section number VII to <b>VIII</b>. Remove: PPM</p>	<p>Renumbered to Section VIII to accommodate new Section VII. Revise reference to acronym for consistency.</p>
<p>IX <del>DIRECTOR- AFFILIATION- WITH OTHER- LABORATORIES</del> TYPE OF CONTROL</p>	<p>Add: parenthetical (<b>including PPM tests</b>) Modify: Section number VIII to <b>IX</b> Delete: <b>Enter the appropriate two digit code from the list below ___ ___ (Enter only one code)</b></p>	<p>Clarified counting of tests to promote accurate test counting. Renumbered to accommodate new Section VII added. Removed extraneous instructions.</p>
<p>X <del>INDIVIDUAL- INVOLVED IN- LABORATORY- TESTING</del> DIRECTOR OF ADDITIONAL LABORATORIES</p>	<p>Modify: caption to read ‘<b>DIRECTOR OF ADDITIONAL LABORATORIES</b>’ Delete: <b>ADDRESS</b> caption and associated lines</p>	<p>Clarified title to describe more clearly the information required. Removed extraneous information to simplify forms completion for laboratory community.</p>
<p>X <del>INDIVIDUAL- INVOLVED IN- LABORATORY- TESTING</del></p>	<p>Delete: <b>entire section, including caption, completion instructions on form, A. Waived testing individuals and B. Nonwaived testing individuals.</b></p>	<p>Based on feedback from State agencies and CMS regional offices, this personnel information is already collected on other forms and is not needs for data analysis. Removed extraneous information to simplify forms completion for laboratory community.</p>