

Revisions to Form CMS-116 v. 3/20/2024, OC and CLIA updates
Clinical Laboratory Improvement Amendments (CLIA) Application Form

Section # on CMS-116	Type of Change	Reason for the Change
Global	Replaced language in ALL CAPS with sentence case	For readability & to align with CMS form standards
Global	Updated all field labels to sentence case	To align with CMS form standards
Global	Replaced Roman numerals with numbers & letters	For usability & to align with CMS form standards
Page 1, top of form	Updated: All applicable sections of this form must be completed. To: Complete all form sections that apply. Please type or print legibly.	To remove passive voice & add “type or print” language from the instructions page
Page 1, bottom of form	Moved the PRA statement to the last page of the form (page 9)	Aligns with how we handle other CMS forms
Page 1, What happens next	Updated: Registration Certificate To: Certificate of Registration	To align language with other certificate types
Section I. General Information		
Mailing/Billing address	Remove all boxes related to the mailing/billing address Replace with CLIA fee coupon email address.	In efforts to transition to paperless certificates/fee coupons
Corporate address	Remove all boxes related to the corporate address.	In efforts to transition to paperless certificates/fee coupons
Email address	Remove the check box to receive notifications including electronic certificates via email. Replace with 2 more boxes for additional email addresses.	In efforts to transition to paperless communication and certificates/fee coupons.
Owner	Add the Name of Owner and the Owner’s phone number	To assist during LD changes and with enforcement issues.
Credentials	Remove credentials.	Must review actual documents sent in providing qualifications/credentials.
Send fee coupon to this address	Remove: "Send fee coupon to this address" along with the checkboxes	In efforts to transition to

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		paperless certificates/fee coupons
Send certificate to this address	Remove: "Send certificate to this address" along with the checkboxes	In efforts to transition to paperless certificates/fee coupons
For Office Use Only	Moved to the top right-hand side of the form.	Better use of space
Section II. Type of Certificate Requested		
Page 2	<p>Replaced: <i>(Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)</i></p> <p>With: Check only one. Select your certificate type based on the highest level of test complexity performed by your laboratory. A laboratory performing non-waived tests can choose Certificate of Compliance or Certificate of Accreditation based on the agency entity you want to survey your laboratory.</p>	Moved this language into the form from instructions for clarity. Changed “agency” to “entity” for clarity.
Certificate of Waiver	Added: can only perform tests categorized as waived*	Moved this language into the form from instructions for clarity
Certificate of Waiver	<p>Make this a NOTE after Certificate of Waiver.</p> <p>Note: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Edited: Proof of these qualifications for the laboratory director must be submitted with this form application.</p>	For clarity & consistency.
Certificate for Provider Performed Microscopy Procedures (PPM)	Added: can only perform tests categorized as PPM, or tests categorized as PPM and waived tests*	Moved this language into the form from instructions for clarity
Certificate of Compliance	Added: can perform tests categorized as waived, PPM and moderate and/or high complexity tests if the applicable CLIA quality standards are met after a CLIA survey.	Moved this language into the form from instructions for clarity
Certificate of Accreditation	Added: can perform tests categorized as waived, PPM and moderate and/ or high complexity non-waived tests if the laboratory is currently accredited by an approved accreditation organization.	Moved this language into the form from instructions for clarity

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Certificate of Accreditation	<p>Updated: Indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.</p> <p>To: If you're applying for a Certificate of Accreditation, you must provide evidence of accreditation by an approved accreditation organization for CLIA purposes, or evidence that you applied for accreditation, within 11 months after you receive your Certificate of Registration. Which organization(s) is your lab accredited by (or you applied for accreditation from) for CLIA purposes?</p>	For plain language & clarity
General	<p>Added footnote: If your accreditation organization isn't listed, contact your local State Agency for instructions.</p> <p>*Get a current list of waived and PPM tests from your State agency.</p> <p>Specific test system categorizations can also be found at Accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm.</p>	Moved this language into the form from instructions for clarity. The state agency does not provide lists.
Section III. Type of Laboratory		
Instructions	Updated instructions at the top of the section: Check the one that most closely describes your facility type:	For plain language & clarity
Instructions	<p>Add to the bottom of the list: Is the laboratory located within a CMS-certified healthcare facility (facilities with asterisk*)? Add a checkbox for Yes or No.</p> <p>Add: If yes, list CMA Certification Numbers (CCNs):</p>	To facilitate expanding laboratory services during a public health emergency
Section IV. Hours of Laboratory Testing		
Hours of Laboratory Testing	Updated instructions: List times when laboratory testing is performed in HH:MM format	For plain language & clarity
Multiple sites?	Remove "check here and attach the additional information using the same format.	Not necessary information
Section V. Multiple Sites		
Instructions	<p>Updated: Must meet one of the regulatory exceptions to apply for this provision in 1-3 below.</p> <p>To: You can only qualify for the multiple site provision (more than one</p>	Moved this language into the form from instructions for clarity

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	<p>site under one certificate) if you meet one of the CLIA requirements described in 42 CFR 493. 493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3). Hospice and HHA could qualify for an exception.</p> <p>You must have a CLIA certificate for each location unless you meet one of the CLIA exceptions described in 42 CFR 493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3).</p>	
Instructions	Edited: If yes, complete the remainder rest of this section	Plain language
Instructions	<p>Update: Indicate which of the following regulatory exceptions applies to your facility's operation.</p> <p>To: Indicate which one of the following regulatory exceptions applies to your facility's operation.</p>	To help clarify instructions.
Instructions	<p>Updated: Questions 1-3</p> <p>1. Is this a laboratory that's not at a fixed location? That is, a laboratory that moves from testing site to testing site (such as a mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations) and may be covered under the certificate of the designated primary site or home base, using its address?..... Yes No</p> <p>If yes, you must include a list of temporary testing sites with this CMS-116 Form. If a mobile unit provides the testing, record the vehicle identification number(s) (VINs) and attach it to the form.</p> <p>2. Is this a not-for-profit or Federal, State, or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites? Yes No</p> <p>If yes, provide the number of sites under the certificate and list name, address and test performed for each site below.</p> <p>3. Is this a hospital with multiple laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction filing for a single certificate for these locations?..... Yes No</p> <p>If yes, provide the number of sites under this certificate and list name or department, location within hospital and specialty/subspecialty areas</p>	For clarity & to reduce number of required responses.

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	<p>performed at each site below.</p> <p>To: 3 statements</p> <p>Indicate which one of the following regulatory exceptions applies to your facility's operation.</p> <p>This is a laboratory that's not at a fixed location that moves from testing site to testing site (such as a mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations) and may be covered under the certificate of the designated primary site or home base, using its address.</p> <p>If selected, you must include a list of temporary testing sites with this CMS-116 Form. If a mobile unit provides the testing, record the vehicle identification number(s) (VINs) and attach it to the form.</p> <p>This is a not-for-profit or Federal, State, or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites.</p> <p>If selected, provide the number of sites under the certificate and list name, address and test performed for each site below.</p> <p>This is a hospital with multiple laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction filing for a single certificate for these locations.</p> <p>If selected, provide the number of sites under this certificate and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.</p>	
Instructions	<p>Updated: If yes, a list of temporary testing sites must be included on or attached to this Form CMS-116. If a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the application.</p> <p>To: If yes, you must include a list of temporary testing sites on or</p>	For plain language & clarity

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	attached to this CMS-116 Form. If a mobile unit provides the laboratory testing, record the vehicle identification number(s) (VINs) and attach it to the form.	
Instructions	Edited: Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?	Plain language
Instructions	Edited: If additional space is needed, Need more space? Check here and attach the additional information using the same format.	For plain language & clarity
Instructions	Removed: In the next three sections, indicate testing performed and estimated annual test volume.	To remove form clutter. This instruction is redundant to the section headers.
Section VI. Waived Testing		
Section VI. Waived Testing	Updated to: Waived Testing to Be Performed	To add clarity
Instructions	Removed: Identify the waived testing (to be) performed by completing the table below.	To remove form clutter. This language is redundant to the table headers & does not add clarity to instructions.
Instructions	Edited: If additional space is needed, Need more space? Check here and attach the additional information using the same format.	For plain language & clarity
Chart	Have text wrap within each box	This allows for a complete Analyte/Test Name /Manufacturer listing.
VII. PPM Testing		
VII. PPM Testing	Updated to: PPM Testing to Be Performed	To add clarity
Instructions	Edited: Listed below are the only PPM tests that can be performed by a facility having with a Certificate for PPM. Mark the checkbox by each PPM procedure that will to be performed.	For plain language & clarity
Instructions	Edited: For laboratories applying for a Certificate of Compliance or Certificate of Accreditation, also include PPM test volume in the specialty/subspecialty category and the “total estimated annual test volume” in section VIII.	“Also” is redundant to “include”
Instructions	Edited: If additional space is needed, Need more space? Check here and attach the additional information using the same format.	For plain language & clarity

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VIII. Non-Waived Testing		
VIII. Non-Waived Testing	VIII. Non-Waived Testing to Be Performed	To add clarity
Instructions	Removed: applying for a Certificate of Compliance or a Certificate of Accreditation.	Redundant to the instruction that only labs applying for these certificates must complete this section
Instructions	Added to the end of instructions for the first table in this section: Specific test system categorizations can be found at: Accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm .	Moved this language into the form from instructions for clarity
Instructions	Edited: If additional space is needed, Need more space? Check here and attach the additional information using the same format.	For plain language & clarity
Other Testing to Be Performed Non-waived test volumes	Added new section header: Other Testing to Be Performed Non-waived test volumes	To better signal to applicants that the questions that follow are for other tests
Instructions	Added bullet formatting	To help applicants better navigate instructions
Instructions	Edited: Place a Check (✓) in the box preceding for each specialty/subspecialty in which the laboratory performs testing.	For plain language & clarity
Instructions	Updated: (For additional guidance on counting test volume, see the instructions included with this application package.) To: Go to Guidelines for Counting Tests on page 9 for more details.	For plain language & clarity
Instructions	Edited: If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/subspecialty for which you're are accredited for CLIA compliance	For plain language & clarity
Instructions	Added: The Accrediting Organization column should reflect accreditation information for CLIA purposes only, e.g., CAP, etc.	Moved this language into the form from instructions for clarity
X. Director Affiliation with Other Laboratories		

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Instructions	Edited: If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete this the following section.	For plain language & clarity
Instructions	Added: Note: For a Certificate for PPM, Certificate of Compliance or Certificate of Accreditation, an individual can serve as the director for no more than five certificates.	Moved this language into the form from instructions for clarity
Signature		
Instructions	<p>Edited: Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.</p> <p>Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.</p> <p>To: Any person who is convicted of intentionally violating any CLIA requirements under section 353(1) of the Public Health Service Act may be imprisoned or fined or both.</p> <p>Consent: The applicant agrees that the laboratory identified in this application will be operated according to the standards set by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant agrees to permit the Secretary, or any designated Federal officer or employee, to inspect the lab and its operations and its pertinent records at any reasonable time, and to furnish any</p>	For clarity and plain language. Rather than adding specificity, the original legalese makes it more difficult for folks to understand what they're agreeing to.

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	requested information or materials necessary to determine the lab's eligibility for its certificate or compliance with CLIA requirements.	
Instructions	Added: Note: "Owner" means any person who owns any interest in a laboratory, except for an interest in a lab whose stock and/or securities are publicly traded. (The purchase of shares of stock or securities on the New York Stock Exchange in a corporation owning a lab would not make a person an owner for the purpose of this regulation.)	Added this language into the form for clarity
	Edit: Print name of Laboratory Director To: Print name of Laboratory Director/Owner Remove: Print name of Laboratory Owner	For clarity with the signature line
Instructions	Added heading: How to Submit Your Form	For plain language & clarity & consistency with other CMS forms
Instructions	Edited: Completed 116 applications must be sent to your local State Agency. Do not send any payment with your completed 116 application. STATE AGENCY CONTACT INFORMATION CAN BE FOUND AT: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf To: Send your completed CMS-116 Form to your local State Agency. Don't send any payment with your form. Find your State Agency contact information at CMS.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf	To make this important instruction clearer & directive.
Instructions Page		
General	Moved the edited contents of this page to be a cover sheet for the CMS-116. Edits remove language that's redundant to form instructions and labels. Edits also remove clarifying details that have been moved into the form as part of this update. and reorganizes general background info with clear headings.	To align with other CMS forms.
	Edited: CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or	For plain language & clarity & to add definition of CLIA

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	<p>treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service are not considered laboratories. CLIA does not apply to a facility that only performs forensic testing. CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition, the CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.</p> <p>The CLIA application (Form CMS-116) collects information about your laboratory's operation which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's laboratory operation. All information submitted should be based on your facility's laboratory operation as of the date of form completion.</p> <p>NOTE: WAIVED TESTS ARE NOT EXEMPT FROM CLIA. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST APPLY FOR A CLIA CERTIFICATE OF WAIVER.</p> <p>To:</p> <p>Clinical Laboratory Improvement Amendments (CLIA) requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain federal requirements.</p> <p>If your facility performs tests for these purposes, it's considered under the law to be a laboratory (lab). CLIA applies even if your lab performs only one or a few basic tests, and even if you're not charging for testing. The CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.</p> <p>The CLIA application (Form CMS-116) collects information about your lab's operation to determine the fees to be assessed, establish baseline data, and fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's lab</p>	<p>acronym</p>

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	<p>operation. Any information you submit should be based on your facility's laboratory operation as of the date you complete the form.</p> <p>Note: Waived tests aren't exempt from CLIA. Facilities that only perform tests categorized as waived must apply for a CLIA certificate of waiver.</p> <p>Facilities that only collect or prepare specimens (or both) or only serve as a mailing service aren't considered labs. CLIA doesn't apply to a facility that only performs forensic testing.</p>	
	<p>Removed:</p> <p><u>1</u>. GENERAL INFORMATION</p> <p>For an initial applicant, check "initial application". For an initial survey or for a recertification, check "survey". For a request to change the type of certificate, check</p> <p>"change in certificate type" and provide the effective date of the change. For all other changes, including change in location, director, lab closure, etc., check "other changes" and provide the effective date of the change.</p> <p>CLIA Identification Number: For an initial applicant, the CLIA number should be left blank. The number will be assigned when the application is processed. For all other applicants, enter the 10-digit CLIA identification number already assigned and listed on your CLIA certificate.</p> <p>Facility Name: Be specific when indicating the name of your facility, particularly when it is a component of a larger entity, e.g., respiratory therapy department in XYZ Hospital. For a physician's office, this may be the name of the physician. NOTE: the information provided is what will appear on your certificate.</p> <p>Email Address: A valid Email Address will be used for communications between the CLIA program and the laboratory. Selecting the RECEIVE NOTIFICATIONS INCLUDING ELECTRONIC CERTIFICATES VIA EMAIL checkbox requires the laboratory to enter a valid Email Address.</p> <p>Physical Facility Address: This address is mandatory and must reflect the physical location where the laboratory testing is performed. The address may include a floor, suite and/or room location, but cannot be a Post Office box or Mail Stop.</p>	<p>Redundant to form instructions & labels.</p> <p>This language adds length to form and contributes to perceived complexity without adding any clarity.</p>

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	<p>If the laboratory has a separate mailing and/or corporate address (from the Facility Address), please complete the appropriate sections on the form.</p> <p>Mailing Address: This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to an alternate location, such as an accounts payable office. A Post Office box number or Mail Stop number may be used as part of the Mailing Address for this form.</p> <p>Corporate Address: This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to another location, such as the main headquarters or home office for the laboratory. A Post Office box number or Mail Stop number may be used as part of the Corporate Address for this section.</p> <p>Form Mailing: Select the address (Physical, Mailing, Corporate) where the CLIA fee coupon and CLIA certificate are to be mailed.</p> <p>For Office Use Only: The date received is the date the form is received by the state agency or CMS regional office for processing.</p>	
	<p>Edited: Proof of these requirements for the laboratory director must be submitted with the application.</p> <p>To: Proof of laboratory director qualifications must be submitted with this form.</p>	For consistency with same language on page 1
	<p>Edited: Individuals who attended foreign schools must have an evaluation of their credentials determining equivalency of their education to education obtained in the United States. Failure to submit this information will delay the processing of your application.</p> <p>To: People who attended foreign schools must have their credentials evaluated to determine U.S. education equivalency. Failure to submit this information will delay the processing of your application.</p>	Plain language and clarity
	<p>Replaced heading: Reminders - Before submitting the Form CMS-116:</p> <p>With new heading: How to submit Form CMS-116</p>	Plain language and to align with other CMS forms.
	Replaced numbers with bullets:	For plain language best

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	<ul style="list-style-type: none"> • Include the current or estimated annual test volume. • For Certificate for PPM, Certificate of Compliance, or Certificate of Accreditation, include the laboratory director qualifications. • Do not send any money with your application. • Send the completed Form CMS-116 to the appropriate State Agency (https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf). 	practices. Numbers denote steps in a process or a hierarchy, and this list is neither.
	Added heading: What happens next	Plain language and to align with other CMS forms.
	<p>Edited: Once the completed Form CMS-116 has been returned to the applicable State agency and it is processed, a fee remittance coupon will be issued. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate, and if applicable the compliance (survey) or validation fee.</p> <p>To: Once you submit Form CMS-116 and your State Agency processes the form, you'll receive a fee remittance coupon. The fee remittance coupon will show your CLIA identification number and the amount due for the certificate, and any compliance (survey) or validation fee that applies.</p>	Plain language and clarity
	Added heading: Get help & more information	Plain language and to align with other CMS forms.
	<p>Edited: If you are applying for a Certificate of Compliance or Certificate of Accreditation, you will initially pay for and receive a Registration Certificate. A Registration Certificate permits a facility requesting a Certificate of Compliance to perform testing until an onsite inspection is conducted to determine program compliance; or for a facility applying for a Certificate of Accreditation, until verification of accreditation by an approved accreditation organization is received by CMS.</p> <p>To: If you're applying for a Certificate of Compliance or Certificate of Accreditation, you'll initially pay for and receive a Registration Certificate. A Registration Certificate permits a</p>	Plain language and clarity

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	facility requesting a Certificate of Compliance to perform testing until an onsite inspection is conducted to determine program compliance; or for a facility applying for a Certificate of Accreditation, until CMS receives verification of accreditation by an approved accreditation organization.	
	Select your certificate type based on the highest level of test complexity performed by your laboratory. A laboratory performing non-waived tests can choose Certificate of Compliance or Certificate of Accreditation based on the agency you wish to survey your laboratory.	Moved into form instructions
	<p>When completing this section, please remember that a facility holding a:</p> <ul style="list-style-type: none"> • Certificate of Waiver can only perform tests categorized as waived;* • Certificate for Provider Performed Microscopy Procedures (PPM) can only perform tests categorized as PPM, or tests categorized as PPM and waived tests;* • Certificate of Compliance can perform tests categorized as waived, PPM and moderate and/or high complexity tests provided the applicable CLIA quality standards are met following a CLIA survey; and • Certificate of Accreditation can perform tests categorized as waived, PPM and moderate and/ or high complexity non-waived tests provided the laboratory is currently accredited by an approved accreditation organization. (If your CMS-approved accreditation organization is not listed, contact your local State Agency for further instructions.) <p>*A current list of waived and PPM tests may be obtained from your State agency. Specific test system categorizations can also be found on the Internet at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/cli.cfm.</p>	Moved into form instructions
<u>II. TYPE OF LABORATORY</u>	<p>Removed: Select the type that is most descriptive of the location where the laboratory testing is performed.</p> <p>If selecting ‘mobile laboratory’ (code 19), a mobile</p>	Redundant to instructions in form

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	<p>laboratory is defined as a movable, self-contained operational laboratory with its own personnel, equipment, and records. For record keeping purposes, include, on a separate sheet of paper, the vehicle identification numbers (VINs) of all vehicles used for mobile laboratory testing.</p> <p>If selecting ‘Practitioner Other’ (code 22), this type includes practitioners such as dentists, chiropractors, etc.</p>	
<u>HOURS OF ROUTINE OPERATION</u>	<p>Removed:</p> <p>Provide only the times when actual laboratory testing is performed in your facility. Please use the HH:MM format and check box marked ‘24/7’ if laboratory testing is performed continuously, e.g., 24 hours a day, 7 days a week. Do not use military time.</p>	Redundant to instructions in form
<u>I. MULTIPLE SITES</u>	<p>You can only qualify for the multiple site provision (more than one site under one certificate) if you meet one of the CLIA requirements described in 42 CFR 493.493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3). Hospice and HHA could qualify for an exception.</p>	Moved into form instructions
	<p>Removed:</p> <p><u>I. WAIVED TESTING</u> Indicate the estimated total annual test volume for all waived tests performed.</p> <p><u>II. PPM TESTING</u> Indicate the estimated total annual test volume for all PPM tests performed.</p>	Redundant to instructions in form
<u>I. NON-WAIVED TESTING (INCLUDING PPM)</u>	<p>The total Estimated Annual Test volume in this section includes all non-waived testing, including PPM tests previously counted in section VII.</p>	Moved into form instructions
	<p>Removed:</p> <p>Follow the specific instructions on page 3 of the Form CMS-116 when completing this section for test counting information.</p>	Redundant to instructions in form

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	(Note: The Accrediting Organization column should reflect accreditation information for CLIA purposes only; e.g., CAP, etc.). Specific test system categorizations can also be found on the Internet at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm .	Moved into form instructions
	Removed: <u>I. TYPE OF CONTROL</u> Select the type of ownership or control which most appropriately describes your facility. <u>II. DIRECTOR OF ADDITIONAL LABORATORIES</u> List all other facilities, including Certificate of Waiver, for which the director is responsible and that are under different certificates.	Redundant to instructions in form
	Note that for a Certificate for PPM, Certificate of Compliance or Certificate of Accreditation, an individual can only serve as the director for no more than five certificates.	Moved into form instructions
	Owner means any person who owns any interest in a laboratory except for an interest in a laboratory whose stock and/or securities are publicly traded. (That is e.g., the purchase of shares of stock or securities on the New York Stock Exchange in a corporation owning a laboratory would not make a person an owner for the purpose of this regulation.)	Moved into signature block instructions