

Revisions to Form CMS-116, Clinical Laboratory Improvement Amendments (CLIA) Application Form

Section # on CMS-116	Type of Change	Reason for the Change
I. GENERAL INFORMATION	In first section, added a checkbox for "Change in Laboratory Director".	Enhances completion of the application
EMAIL ADDRESS	Revised the language for this checkbox from "Receive future notifications via email" to "Receive notifications including electronic certificates via email"	Clarifies how emails will be used.
PRA Statement bottom of page 1	Revised the last sentence to remove the link to LabExcellence@cms.hhs.gov . Questions or concerns regarding where to submit CLIA documents should be sent to either the State Agency CLIA contacts (https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/cliasa.pdf) or the CLIA Operations Branch Contacts (https://www.cms.gov/files/document/clia-operations-branch-contacts.pdf).	Clarifies who to contact for questions about the CMS-116 and where to submit the CMS-116
V. MULTIPLE SITES	For the first bullet, added the sentence "A list of temporary testing sites must be included on or attached to the Form CMS-116."	Communicates more clearly what is needed.
	Add "the" before the word "remainder" in the text preceding the Yes checkbox.	Editorial correction
	For the second bullet, added a comma after the word "State"	Editorial correction
VIII. NON-WAIVED TESTING	Removed the second instance of a duplicate sentence. Sentence removed was "If additional space is needed, check here and attach additional information using the same format." Include text box similar to Section VII."	Enhances completion of the application
	To the last sentence, remove extra space after A2LA. Added a space before CAP and added a comma after COLA.	Editorial correction

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IX. TYPE OF CONTROL	<p>Revised the question from: "Does this facility have partial or full ownership by a foreign entity or foreign government?" to: "Does this facility have partial or full ownership or control by a non-United States-based government or entity?"</p> <p>In addition, the text was bolded.</p>	<p>Communicates more clearly what is needed.</p> <p>Enhances completion of the application</p>
Instructions for Completion	<p>Revised the bullet for documentation of education from "Education (copy of Diploma, transcript from accredited institution, CMEs)," to "Education (documentation necessary to ensure CLIA personnel qualifications are met, e.g., diploma, transcript)"</p>	<p>Communicates more clearly what is needed.</p>
	<p>Revised the last sentence under Email Address from: Selecting the RECEIVE NOTIFICATIONS VIA EMAIL checkbox, requires the laboratory to enter a valid Email Address. To: Selecting the RECEIVE NOTIFICATIONS INCLUDING ELECTRONIC CERTIFICATES VIA EMAIL checkbox requires the laboratory to enter a valid Email Address.</p>	<p>Clarifies how emails will be used.</p>
	<p>For the first sentence under Corporate Address, removed the comma after the words "such as"</p>	<p>Editorial correction</p>
	<p>For the last sentence under III.TYPE OF LABORATORY, removed the comma after the words "such as".</p>	<p>Editorial correction</p>
	<p>For the sections VII. PPM TESTING, VIII.NON-WAIVED TESTING, IX.TYPE OF CONTROL, and X.DIRECTOR OF ADDITIONAL LABORATORIES, moved the underlining so that only the heading was underlined.</p>	<p>Editorial correction</p>

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	For the section VIII.NON-WAIVED TESTING, added the sentence "Specific test system categorizations can also be found on the Internet at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/cliia.cfm ."	Enhances completion of the application
	For the first sentence under X.DIRECTOR OF ADDITIONAL LABORATORIES, added the text ", including Certificate of Waiver,".	Communicates more clearly what is needed.
	Under X.DIRECTOR OF ADDITIONAL LABORATORIES, revised "'Certificate of PPM," to "'Certificate for PPM,"	Editorial correction
	Added this language after Section X: 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.)	Enhances completion of the application
TESTS COMMONLY PERFORMED AND THEIR CORRESPONDING LABORATORY SPECIALTIES/SUBSPECIALITIES	In the header, corrected the spelling of the word "SUBSPECIALITIES" to "SUBSPECIALTIES".	Editorial correction

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	<p>Under the heading General Immunology (220), revised: “Antigen/Antibody (hepatitis, herpes, rubella, etc.) Complement (C3, C4) Immunoglobulin HIV” to: “Antibody (herpes, rubella, etc.) Complement (C3, C4) Hepatitis (Antigen/Antibody) HIV (Antigen/Antibody) Immunoglobulin”</p>	<p>Enhances completion of the application</p>
	<p>At the bottom of page 9, removed the sentence "Other non-waived tests and their specialties/ subspecialties can be found at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/SubjecttoCLIA.pdf and https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/lccodes.pdf."</p>	<p>Links are obsolete and not maintained by the CMS CLIA program.</p>
<p>GUIDELINES FOR COUNTING TESTS FOR CLIA</p>	<p>Under the bullet for histocompatibility, revised the words “cross match” to one word "crossmatch".</p>	<p>Editorial correction</p>
	<p>Revised “Genetics tests should be placed in the specialty or subspecialty where they fit best, according to the methodology of the test.” to “Genetics testing platforms are used in many of the testing specialties/subspecialties. The laboratory should select the specialty or subspecialty according to the analyte the test is identifying.”</p>	<p>Technical correction to reflect current interpretation. Enhances completion of the application</p>