

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	<p>Add section prior to this part to say "ALL APPLICABLE SECTIONS OF THIS FORM MUST BE COMPLETED."</p> <p>Add line under Initial Application to collect "Anticipated Start Date" that includes spaces for the date.</p> <p>Insert the following: <input type="checkbox"/> RECEIVE FUTURE NOTIFICATIONS VIA EMAIL</p> <p>Move both Federal Tax Identification Number, Telephone no, and FAX no. fields up. The new checkbox about receiving emails could then be in a field across from the email address field.</p> <p>Add "(Pick one)" after text for both the Send Fee Coupon to this Address and the Send Certificate to this Address sections.</p> <p>Add a box to collect "Laboratory Director's Phone Number"</p>	<p>Enhances completion of application</p> <p>Enhances completion of application</p> <p>Needed for going paperless.</p> <p>Enhances completion of application</p> <p>Enhances completion of application</p>
VI.WAIVED TESTING	<p>To the first section before section VI, add the word "estimated" before the word "annual"</p> <p>Change current language (i.e., Identify the waived testing (to be) performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory. e.g. (Rapid Strep, Acme Home Glucose Meter)) to "Identify the</p>	<p>Communicates more clearly</p> <p>Enhances completion of application</p>

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	<p>waived testing (to be) performed by completing the table below. Be as specific as possible. Include each analyte, test system, or device used in the laboratory.”</p> <p>Add table for what is needed</p>	<p>Enhances completion of application & communicates more clearly</p>
VII. PPM TESTING	<p>Change current language (i.e., Identify the PPM testing (to be) performed. Be as specific as possible. e.g. (Potassium Hydroxide (KOH) Preps, Urine Sediment Examinations)) to “Listed below are the only PPM tests that can be performed by a facility having a Certificate for PPM. Mark the checkbox by each PPM procedure(s) to be performed.</p> <p>Insert checkbox list of PPM testing.</p>	<p>Enhances completion of application & communicates more clearly</p> <p>Enhances completion of application & communicates more clearly</p>
VIII. NON-WAIVED TESTING	<p>Change current language (i.e., Identify the non-waived testing (to be) performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory e.g. (Potassium, Acme Chemistry Analyzer).) to “Identify the non-waived testing (to be) performed by completing the table below. Be as specific as possible. This includes each analyte test system or device used in the laboratory. Use (M) for moderate complexity and (H) for high complexity.</p>	<p>Enhance completion of application</p>

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IX. Type of Control	<p>Add a new section below the first one for IX and before the Voluntary Nonprofit/For Profit/Government section to include: Does this facility have partial or full ownership by a foreign entity or foreign government? No _____ Yes _____ If yes, what is the country of origin for the foreign entity? _____</p> <p>Under the Government Section: Change "Specify" to: If 09 is selected, please specify the country or the province.</p>	<p>Enhance completion of application</p> <p>Enhance completion of application</p>
Bottom of Page 5 of currently approved form	<p>Add a new row to collect the printed name of the owner. I suggest calling this box "PRINT NAME OF OWNER OF LABORATORY"</p> <p>In the signature of owner/director of laboratory field change wording ('Sign in ink' to "(Sign in ink or use a secure electronic signature)").</p>	<p>Communicate more clearly</p> <p>To allow for a secure electronic signature.</p>
Instructions for Completion	<p>For the last sentence of the first paragraph, insert a comma after "In addition"</p> <p>Insert a new paragraph for email address: Email Address: A valid Email Address is</p>	<p>Editorial correction</p> <p>Enhance completion of application Coincides with change made to Section I</p>

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	<p>optional and will be used for communications between the CLIA program and the laboratory. Selecting the RECEIVE NOTIFICATIONS VIA EMAIL checkbox, requires the laboratory to enter a valid Email Address.</p> <p>Under II. TYPE OF CERTIFICATE REQUESTED make the text “Certificate of Waiver can only perform tests categorized as waived;*” a bulleted item similar to the bullet for Certificate for Provider Performed Microscopy Procedures.</p>	<p>GENERAL INFORMATION</p> <p>Editorial correction.</p>
<p>GUIDELINES FOR COUNTING TESTS FOR CLIA</p>	<p>Except for the last bullet, re-arrange so that it is organized by the BOLDED text?</p> <p>Text changes made to bullets for histocompatibility, microbiology, cytology, clinical cytogenetics, and chemistry.</p> <p>Add new bullet for genetic tests and flow cytometry.</p>	<p>Communicate more clearly</p> <p>Updated to reflect what is in the State Operations Manual, Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services</p> <p>Updated to reflect what is in the State Operations Manual, Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services</p>