

Division of Quality Assurance
CLIA – Frequently Asked Questions
June 2013

Question	Answer	Federal requirement
1) Who needs a CLIA certificate?	Any facility where testing is performed on specimens collected from human beings for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of health, comes under the Federal CLIA requirements.	§ 493.2 Definitions
2) What are the types of CLIA certificates?	There are four different CLIA certificates: <ul style="list-style-type: none"> • Certificate of Waiver • Provider Performed Microscopy • Certificate of Compliance • Certificate of Accreditation 	§ 493.5 Categories of tests by complexity
3) What does “CLIA Certificate of Waiver” mean?	This Certificate allows the laboratory to perform any test that has been categorized by the FDA as a “waived” method. An example of waived testing is many of the finger-stick blood glucose methods. This DOES NOT mean that the laboratory is waived from all CLIA requirements.	§ 493.15 Laboratories performing waived tests
4) What are the requirements for a CLIA Certificate of Waiver?	Requirements include: <ul style="list-style-type: none"> • follow the manufacturer’s instructions for all tests performed; • agree to permit announced and unannounced inspections by CMS and its authorized agents; • notify the state agency within 30 days of any changes in – <ul style="list-style-type: none"> ○ Ownership ○ Name ○ Location, or ○ Director • Remit the Certificate of Waiver fee 	§ 493.35 Application for a Certificate of Waiver § 493.37 Requirements for a Certificate of Waiver, and § 493.39 Notification requirements for a Certificate of Waiver
5) How do I determine what type of CLIA Certificate is required?	If the only tests the lab performs are categorized by the FDA as “waived” methods, the laboratory will need to obtain a Certificate of Waiver. If the test menu includes waived, PPM procedures, moderate and/or high complexity methods, the determination of type of certificate is based on these three factors: <ul style="list-style-type: none"> • FDA categorization of the tests performed; • Qualifications of personnel performing the tests; and • For Compliance or Accreditation certificates, the agency that will be 	§ 493.15 § 493.43 Application for a Certificate for Provider Performed Microscopy or a Certificate of Compliance § 493.55 Application for a Certificate of Accreditation

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	responsible for the survey/inspection.	
6) How do I apply for a CLIA certificate?	<p>Complete the CLIA application form, CMS-116, and submit it to the state agency along with a copy of the Laboratory Director's State of Wisconsin license (see state agency contact info below).</p> <p>The CMS-116 can be accessed at: http://www.cms.gov/cmsforms/downloads/cms116.pdf</p> <p>Additional information is needed if applying for a Certificate of Compliance or Accreditation.</p> <p>Please note: Laboratory Director license verification printed from a public domain resource on the web are not acceptable.</p>	<p>§ 493.35</p> <p>§ 493.43</p> <p>§ 493.55</p>
7) Who can sign the CMS-116 form?	<p>The CMS-116 form must be signed by either the Laboratory Director, the owner, or an authorized representative.</p> <p>If signed by an owner or authorized representative, please print the individual's name and title underneath their signature.</p>	<p>§ 493.35</p> <p>§ 493.43</p> <p>§ 493.55</p>
8) What if my Laboratory Director does not have State of Wisconsin licensure?	Contact the state agency for assistance.	NA
9) How is my certificate of Waiver renewed? How is my certificate of PPM renewed?	<p>The federal contractor sends an invoice approximately 6 months prior to the certificate expiration date.</p> <p>This invoice includes the fee coupon and the address that you submit your check to.</p> <p>DO NOT mail payment to the state agency.</p>	NA
10) When do I receive my new certificate of Waiver?	After payment is received, the federal contractor mails out the new certificate shortly before the old one is due to expire. This may be the week your current certificate expires.	NA
11) How is my certificate of	The federal contractor sends an invoice for the compliance fee	NA

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Compliance renewed?	<p>approximately 1 year prior to the expiration date.</p> <p>Once the compliance fee is paid, and not more than two weeks prior to the survey, the CLIA surveyor contacts the laboratory to announce the on-site survey date.</p> <p>After the compliance survey is completed and with a finding that all CLIA requirements are met, the federal contractor sends an invoice for the certificate fee.</p> <p>Once this certificate fee is paid, the federal contractor mails the new CLIA certificate.</p>	
12) How is my certificate of Accreditation renewed?	<p>The federal contractor sends an invoice for the certificate fee and validation fee approximately 6 months prior to the certificate expiration date.</p> <p>Once the certificate and validation fee is paid and shortly before the current certificate expires, the federal contractor sends the new CLIA certificate.</p>	NA
13) Who do I send payment to?	<p>The address for the federal contractor is:</p> <p>CLIA Laboratory Program PO Box 530882 Atlanta GA 30353-0882</p> <p>Please include your CLIA number on the front of all checks sent to the contractor.</p> <p>DO NOT bundle fee payment to the contractor.</p>	NA
14) What are the notification requirements for a PPM certificate? What are the notification requirements for a Certificate of Accreditation?	<p>Notify the state agency within 30 days of any change in:</p> <ul style="list-style-type: none"> • Ownership, • Name, • Location, and/or • Laboratory Director 	<p>§ 493.53 Notification requirements for laboratories issued a certificate for Provider Performed Microscopy</p> <p>§ 493.63 Notification requirements for laboratories issued a certificate of Accreditation</p>
15) What are the notification requirements for a Certificate of	<p>Notify the state agency within 30 days of any change in:</p> <ul style="list-style-type: none"> • Ownership, 	§ 493.51 Notification requirements for laboratories issued a certificate

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Compliance?	<ul style="list-style-type: none"> • Name, • Location; • Director, or • Technical Supervisor <p>Notify the state agency within 6 months of any addition or deletion of a test specialty.</p>	of Compliance
16) How do I notify the state agency of changes to my CLIA certificate?	<p>Written notification is required for all change requests.</p> <p>The CMS-116 form is required for:</p> <ul style="list-style-type: none"> • status change to any certificate type other than Waiver • Laboratory Director change to a Certificate of PPM, Compliance or Accreditation • Reinstatement of a CLIA certificate <p>The CMS-116 form can be accessed at: http://www.cms.gov/cmsforms/downloads/cms116.pdf</p> <p>All other changes - acceptable written documents include emails, faxes, or hard copy letters and must include the following:</p> <ul style="list-style-type: none"> • CLIA number • Laboratory name • Change requested, and • Name and full contact info for the person requesting the change 	SOM 6032 Notification of change in laboratory operations
17) How do I know that the state agency has processed my application request or change request?	<p>The state agency sends a confirmation letter to the individual that submitted the application and/or change request. Processing is usually completed within two weeks of receipt of all necessary forms and licenses.</p> <p>Note: Providing an email address is appreciated as we prefer to send confirmation letters electronically.</p> <p>Retain this confirmation letter with your CLIA certificate.</p>	NA
18) How can I keep current with CLIA requirements and state agency	Sign up for the Division of Quality Assurance's (DQA) email subscription services at: http://www.dhs.wisconsin.gov/rl_DSL/Listserv/signup.HTM	NA

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information?		
19) Where can I find more information about the CLIA regulations?	The CLIA regulations and related information can be found on the CMS website at: http://www.cms.gov/CLIA/	NA
20) Where can I find assistance in performing Waived testing?	The CDC has prepared information specifically for Waived testing. The program is called "Ready?,Set?, Test!" . Further information is available at this link: http://www.cdc.gov/dls/waivedtests	NA
21) Who do I report problems to: Test system problems Complaints about laboratory services	Report to the FDA MedWatch program: http://www.fda.gov/Safety/MedWatch/default.htm Report to the state agency by: <ul style="list-style-type: none">• phone 800.642.6552• online complaint system available at: http://www.dhs.wisconsin.gov/bqaconsumer/HealthCareComplaints.htm	NA
22) What is the state agency contact info?	Mailing address is: DHS/DQA/BHS – CLIA Section 1 W Wilson St Rm 455 PO Box 2969 Madison WI 53701-2969 Ph # 608-266-7485 Fax # 608-264-9847 Email: angela.mack@dhs.wisconsin.gov or DHSDQACLIA@wisconsin.gov	NA