

COV19 Antigen Testing - Waived



Laboratories

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10.8.2020 | Karl A. Krogman MHA, MT (ASCP)^{cm}

Objectives

- Review regulatory requirements
- Provide an overview of the initial setup and training
- Go over general best practices and potential challenges
- Identify COVID reporting requirements



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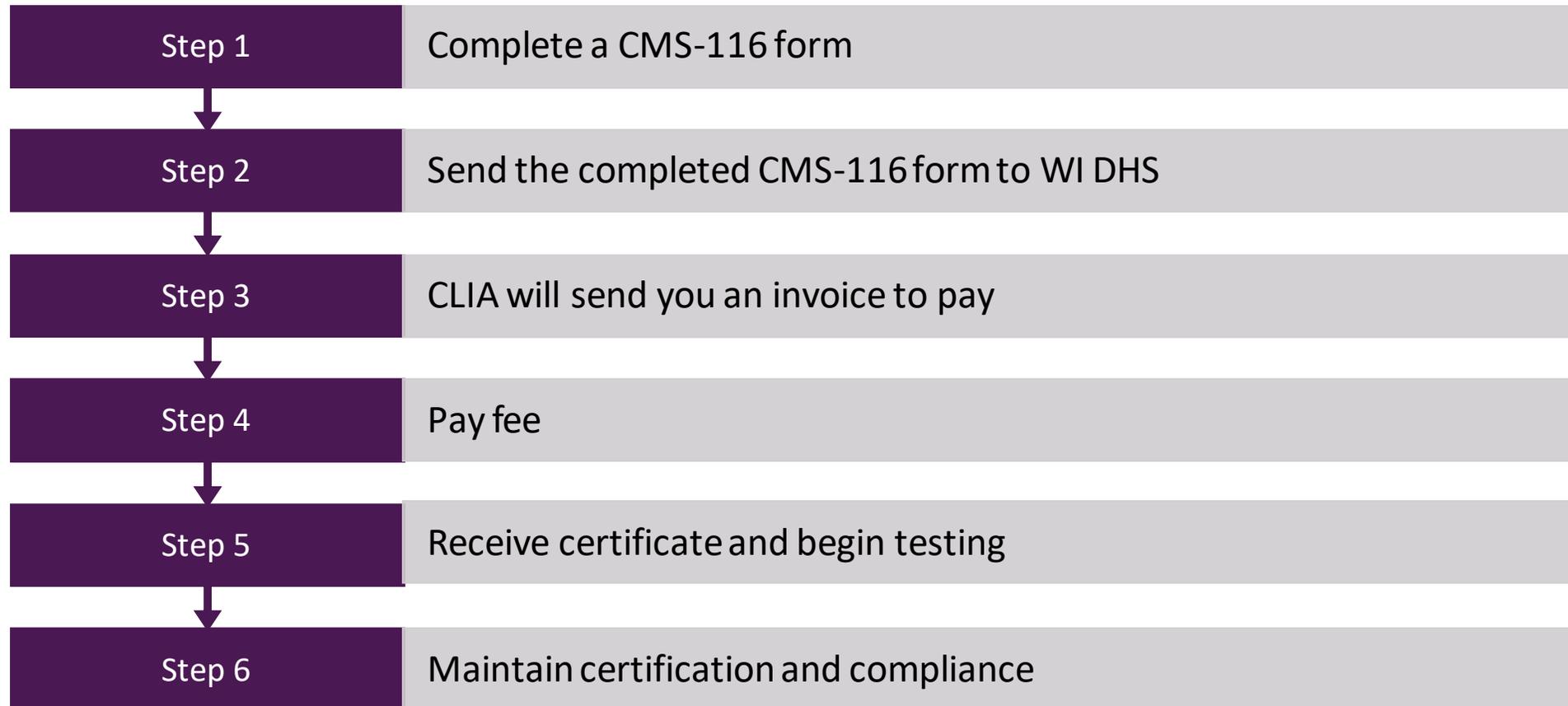
Regulatory Requirements

- Waived Testing Explanation
 - Simple tests with a low risk for an incorrect result
 - Performed without routine regulatory oversight
 - Cleared by the FDA and meets CLIA criteria
- Need to obtain a CLIA Certificate of Waiver (COW)
 - One per physical address where testing is performed (few exceptions)
 - Certification must be renewed every two years
 - Sites do not go through annual inspections
 - Must follow manufacturer's instructions
 - Sites should maintain quality logs and employee competencies



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How do I obtain a CLIA license?



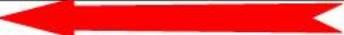
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**CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION**

I. GENERAL INFORMATION

<input checked="" type="checkbox"/> Initial Application <input type="checkbox"/> Survey <input type="checkbox"/> Change in Certificate Type <input type="checkbox"/> Other Changes (Specify) _____ Effective Date _____			CLIA IDENTIFICATION NUMBER _____ D _____ <i>(If an initial application leave blank, a number will be assigned)</i>		
FACILITY NAME			FEDERAL TAX IDENTIFICATION NUMBER		
EMAIL ADDRESS			TELEPHONE NO. (Include area code)	FAX NO. (Include area code)	
FACILITY ADDRESS — <i>Physical Location of Laboratory (Building, Floor, Suite if applicable.) Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified</i> NUMBER, STREET (No P.O. Boxes)			MAILING/BILLING ADDRESS (if different from facility address) send Fee Coupon or certificate NUMBER, STREET		
CITY	STATE	ZIP CODE	CITY	STATE	ZIP CODE
SEND FEE COUPON TO THIS ADDRESS		SEND CERTIFICATE TO THIS ADDRESS		CORPORATE ADDRESS (if different from facility) send Fee Coupon or certificate	
<input type="checkbox"/> Physical <input type="checkbox"/> Mailing <input type="checkbox"/> Corporate		<input type="checkbox"/> Physical <input type="checkbox"/> Mailing <input type="checkbox"/> Corporate		NUMBER, STREET	
NAME OF DIRECTOR (Last, First, Middle Initial)			CITY	STATE	ZIP CODE
CREDENTIALS			FOR OFFICE USE ONLY Date Received _____		

II. TYPE OF CERTIFICATE REQUESTED (Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)

- Certificate of Waiver (Complete Sections I – VI and IX – X) 
- Certificate for Provider Performed Microscopy Procedures (PPM) ((Complete Sections I-VII and IX-X)
- Certificate of Compliance (Complete Sections I – X)
- Certificate of Accreditation (Complete Sections I – X) and 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.
 - The Joint Commission AAHHS/HFAP AABB A2LA
 - CAP COLA ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

CMS-116 Example

WISCONSIN DEPARTMENT OF HEALTH SERVICES
Division of Quality Assurance
Clinical Laboratory Section
1 West Wilson Street
P.O. Box 2969
Madison, WI 53701-2969
Phone: (608) 261-0654
Fax: (608) 283-7462
Email: DHSDQACLIA@dhs.wisconsin.gov



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**CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF COMPLIANCE**

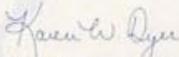
<p>LABORATORY NAME AND ADDRESS LABORATORY 12345 MAIN STREET SPRINGFIELD, ST 67890</p>	<p>CLIA ID NUMBER 22D0981035</p>
<p>LABORATORY DIRECTOR JACOB LEE Ph.D.</p>	<p>EFFECTIVE DATE 12/02/2018</p> <p>EXPIRATION DATE 12/01/2020</p>

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.



CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES



Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

CLIA Fee Coupon

Payment Due Date: 08/07/2020 Total Payment Due: \$180.00

Make check payable to: CLIA Laboratory Program

CLIA ID Number: 22D0981035 Do not send name or address changes with your remittance

STATE UNIVERSITY HEALTH SYSTEM
12345 MAIN STREET
1ST FLOOR
SPRINGFIELD, ST 67890

Mail check to:
CLIA LABORATORY PROGRAM
P.O. BOX 3056
PORTLAND, OR 97208-3056

21 BILLS_052320

09810350000000000000200623000018000000000000000000000000



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Initial Lab Setup



Procedures



Training



Quality Program



Safety
Considerations



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Procedures

- CLIA does not require that sites have a written policy in place for waived testing, but it is recommended
 - Must follow manufacturer's recommendations
 - Should keep an up to date copy on file



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Training & Competency



Must have a Laboratory Director (LD)



Testing personnel should have documentation proving they are competent to collect and perform the testing



Proficiency Testing (PT) is not required for Waived testing



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Training & Competency – Items to Consider

- Provide specific training to the testing personnel so that you are certain they:
 - Collect and label specimens properly
 - Understand the manufacturer's instructions
 - Know how to perform and document test results
 - Are able to identify instrument issues
- Observe and evaluate your testing personnel to make certain the testing is accurate.
- Initial and annual competency assessments are required for waived test systems



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SINGLE TEST SYSTEM COMPETENCY FORM

Employee: _____ Employee I. D.: _____
 Site: _____ Year: _____
 Department/Area: _____ Initial Semi-annual Annual
 Test System: _____ Waived Non-waived

All applicable, six elements of competency must be documented, initially, semi-annually, and annually, for non-waived test systems. Initial and annual competency assessment is required for waived test systems, but not all six elements are required. The laboratory may select which element to assess for each waived test system. Annually is defined as every 12 months plus/minus 30 days.

Element 1 Direct observation of routine patient test performance, including, as applicable, patient identification and preparation, and specimen collection, handling, processing, and testing.			
Observe Patient Identification	Date: Assessor Initials:	Policy #	<input type="checkbox"/> N/A
Observe Specimen Collection	Date: Assessor Initials:	Policy #	<input type="checkbox"/> N/A
Observe Handling/Processing	Date: Assessor Initials:	Policy #	<input type="checkbox"/> N/A
Observe Patient Testing	Date: Assessor Initials:	Sample # Policy #	<input type="checkbox"/> N/A
Element 2 Monitoring the recording and reporting of test results including, as applicable, reporting of critical results.			
Reporting Normals	Date: Assessor Initials:		<input type="checkbox"/> N/A
Reporting Criticals	Date: Assessor Initials:		<input type="checkbox"/> N/A
Element 3 Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records.			
Review Intermediate Test Results	Date: Assessor Initials:		<input type="checkbox"/> N/A
Review Quality Control	Date: Assessor Initials:		<input type="checkbox"/> N/A
Review Preventative Maintenance	Date: Assessor Initials:		<input type="checkbox"/> N/A
Review Proficiency Testing	Date: Assessor Initials:		<input type="checkbox"/> N/A
Element 4 Direct observation of performance of instrument maintenance and function checks.			
Observe Instrument Maintenance	Date: Assessor Initials:	Policy #	<input type="checkbox"/> N/A
Element 5 Assessment of test performance through testing previously analyzed specimens, internal blind testing samples OR external proficiency testing samples. (Attach documentation for previously analyzed samples.)			
Assess Proficiency Testing, Blind Sample, OR Previously Analyzed Samples	Date: Assessor Initials:	Sample #	<input type="checkbox"/> N/A
Element 6 Evaluation of problem-solving skills.			
Evaluate Problem Solving (Describe below.)	Date: Assessor Initials:		<input type="checkbox"/> N/A

Assessment of Test Performance: Satisfactory Unsatisfactory

The employee's signature indicates that he/she has read and understands all of the ACL Laboratories' policies that are listed above and has had the opportunity to review and ask questions about policies and procedures related to the equipment and testing above. This employee is deemed to be competent to perform unsupervised patient testing in the above test system.

Employee Signature: _____ Date: _____
 Assessor Signature: _____ Date: _____

The 6 Elements of Competency

1. Direct observation of testing
2. Monitoring test results
3. Quality review
4. Direct observation for any instrument maintenance
5. Assessment of test performance
6. Evaluation of problem-solving skills



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Key Takeaways -Competency

- Document that your testing personnel have read the manufacturer's instructions
- Document that your testing personnel have been shown how to perform the test
- Document that the individual was observed successfully performing the test
- This should be done initially when setting up the instrument and once a year after that



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Quality Control Testing

There are two types of controls that can be used to ensure waived testing is accurate:

- **Internal** (also known as built-in or procedural controls)
 - Ensure that the test is working as expected
 - That enough of the sample was added
- **External**
 - Act as controlled patient samples to ensure testing process is properly performed

How often should we run controls?

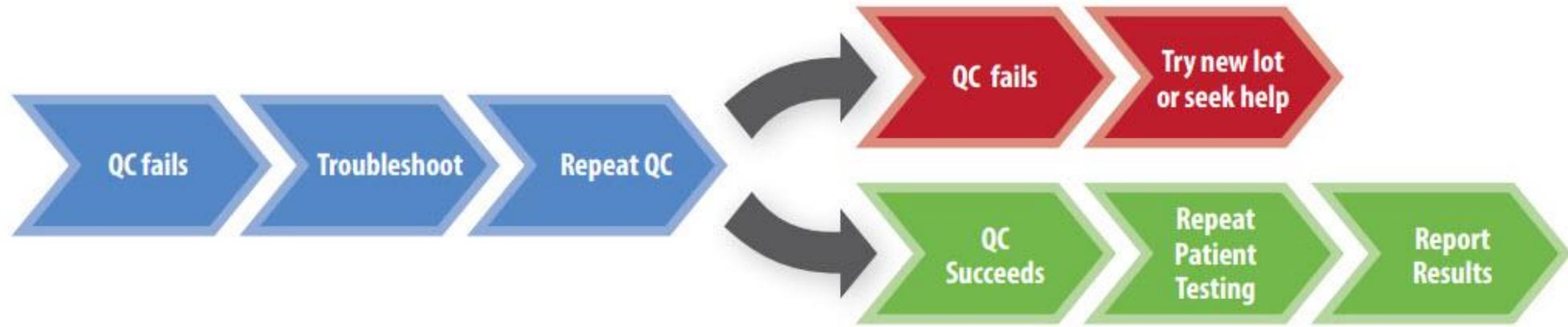
- Follow the manufacturer's instructions or site policy
- Recommended:
 - With each new lot or shipment
 - With each new operator
 - At minimum once a month or in accordance with accreditation requirements

Note –CLIA does require the documentation and tracking of QC results



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What actions are needed if QC is out?





SOFIA SARS ANTIGEN FIA, PATIENT WORKSHEET
(INTERNAL QC)

Kit: Sofia SARS Antigen FIA Kit
Manufacturer: Quidel Corporation

Lot # _____
Exp. Date _____

EXPECTED INTERNAL QC RESULTS: (Record with each patient)

Procedural Control: Valid

Note: For non-waived testing, daily external QC is required unless testing laboratory has completed an IQCP.

Date	Patient ID	Procedural Control Expected Results: Valid	Patient Result		Tech	Manual Entry Verified By
			POS	NEG		
		<input type="checkbox"/> Expected results present				
		<input type="checkbox"/> Expected results not present				
		<input type="checkbox"/> Expected results present				
		<input type="checkbox"/> Expected results not present				
		<input type="checkbox"/> Expected results present				
		<input type="checkbox"/> Expected results not present				
		<input type="checkbox"/> Expected results present				
		<input type="checkbox"/> Expected results not present				
		<input type="checkbox"/> Expected results present				
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		<input type="checkbox"/> Expected results present				
		<input type="checkbox"/> Expected results not present				
		<input type="checkbox"/> Expected results present				
		<input type="checkbox"/> Expected results not present				
		<input type="checkbox"/> Expected results present				
		<input type="checkbox"/> Expected results not present				

Reviewed by: _____ Date: _____

Facility: Dr. Smith's Office
Location: 123 Main Street
Atlanta, GA 55555

TEMPERATURE LOG

Refrigerator/freezer Location Lab refrigerator Month/Year June 2019
Acceptable temperature range 4-8°C

Date	Temperature	Checked by:	Date	Temperature	Checked by:
1	4°C	Sara	17	#	#
2	#	#	18	4°C	Sara
3	#	#	19	4°C	Sara
4	4°C	Sara	20	4°C	CO
5	4°C	Sara	21	4°C	Sara
6	8°C	CO	22*	24°C	Sara
7*	15°C	Sara	23	#	#
8	4°C	Sara	24	#	#
9	#	#	25	4°C	Sara
10	#	#	26	4°C	Sara
11	4°C	Sara	27	4°C	CO
12	4°C	Sara	28	4°C	Sara
13	4°C	CO	29	4°C	Sara
14	4°C	Sara	30	#	#
15	4°C	Sara	31	#	#
16	#	#			

* Enter # for weekends and holidays when temperature is not monitored.

Corrective Action for Out of Range Temperature

Date	Action Taken	Initials
* 6/7	Refrigerator door was ajar. Closed door, check in 30 minutes. Temp at 6°C - OK.	Sara
* 6/22	Refrigerator not staying in range. Called for service. Door seal replaced. QC'd kits stored in refrigerator. Continue to QC and monitor for problems.	Sara

Reviewed by: Janice Smith, office mgr.

Date: 6/29/2019



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Laboratory Best Practices

- Do not use kit contents beyond the expiration date
- Use appropriate precautions when collecting, handling, and disposing of samples
- Monitor the room temperature and store reagents and kits as directed
- Use proper PPE: protective clothing, gloves, and eye/face protection
- Review the manufacturer's instructions with each new lot to ensure there were no changes



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Testing Preparation

- Clean work surfaces both before and after testing
 - A 10% bleach solution is recommended
 - (1 part bleach to 9 parts water)
- Verify reagent/kit expiration dates
 - Do not use reagents from another kit or lot
- Be sure you can properly identify the source patient and sample throughout the process
 - Assign an identifier and label or write it on both the sample and cassette
- Samples positive for COVID should be treated as biohazardous waste and disposed properly



Limitations

- Use of viral transport media may result in decreased test sensitivity, and directly testing specimens is recommended.
- Remel M4 and M4RT should not be used in with the Sofia SARS Antigen FIA Assay in the Sofia. Some lots of M4 and M4RT have been shown to cause false positive results when used with the Sofia SARS Antigen FIA Assay.
- The contents of this kit are to be used for the qualitative detection of SARS antigens from nasal swab and nasopharyngeal swab.
- This test detected both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- Negative results, from patients with symptom onset beyond five days, should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.



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Reporting to the Department of Health and Human Services (HHS)

- The reporting of all results is **required** for HHS and CMS.
 - These can be uploaded to WLR every day you perform testing
 - The data is forwarded on to the WI Electronic Disease Surveillance System (WEDSS) for state reporting and to the CDC for HHS and CMS reporting



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References

- <https://www.cms.gov/files/document/cms-clia-laboratory-quick-start-guide-remediated.pdf>
- <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>
- <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf>
- <https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html>
- https://www.cdc.gov/labquality/images/waived-tests/RST-Booklet_Dec-2019.pdf



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Questions?