COV19 Antigen Testing - Waived

10.8.2020 | Karl A. Krogman MHA, MT (ASCP)
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
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
### How do I obtain a CLIA license?

<table>
<thead>
<tr>
<th>Step</th>
<th>Task</th>
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</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Complete a CMS-116 form</td>
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<tr>
<td>Step 2</td>
<td>Send the completed CMS-116 form to WI DHS</td>
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<tr>
<td>Step 3</td>
<td>CLIA will send you an invoice to pay</td>
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<td>Step 4</td>
<td>Pay fee</td>
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<tr>
<td>Step 5</td>
<td>Receive certificate and begin testing</td>
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<tr>
<td>Step 6</td>
<td>Maintain certification and compliance</td>
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# 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

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

### I. GENERAL INFORMATION

- **Initial Application**
- **Change in Certificate Type**
- **Other Changes (Specify)**

#### Effective Date

<table>
<thead>
<tr>
<th>FACILITY NAME</th>
<th>FEDERAL TAX IDENTIFICATION NUMBER</th>
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<tr>
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<th>TELEPHONE NO. (Include area code)</th>
<th>TAX NO. (Include area code)</th>
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#### FACILITY ADDRESS — Physical Location of Laboratory (Building, Floor, Suite)

<table>
<thead>
<tr>
<th>NUMBER, STREET</th>
<th>Mailing/Receiving Address (if different from facility address) and Fee Coupon or Certificate</th>
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#### CITY  STATE  ZIP CODE

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#### SEND FEES COUPON TO THIS ADDRESS

- Physical  
- Mailing  
- Corporate

<table>
<thead>
<tr>
<th>CORPORATE ADDRESS (if different from facility address) and Fee Coupon or Certificate</th>
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</table>

<table>
<thead>
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### 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
  - AAHSHFAP
  - 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.
Initial Lab Setup

- Procedures
- Training
- Quality Program
- Safety Considerations
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
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
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
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
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
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
What actions are needed if QC is out?
**EXCEPTED INTERNAL QC RESULTS**: (Record with each patient)

Procedural Control: Valid

Notes: For non-sampled testing, daily external QC is required unless testing laboratory has completed an IDCP.

<table>
<thead>
<tr>
<th>Date</th>
<th>Patient ID</th>
<th>Procedural Control</th>
<th>Expected Results</th>
<th>Patient Result</th>
<th>Tech</th>
<th>Manual Entry Verified By</th>
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<table>
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**TEMPERATURE LOG**

Refrigerator/freezer Location: Lab refrigerator

Acceptable temperature range: 4-8°C

**Corrective Action for Out of Range Temperature**

- 6/7: Refrigerator door was ajar. Closed door, check in 30 minutes. Temp at 8°C - Ok.
- 6/22: Refrigerator not keeping in range. Called for service. Box was replaced. OK. Temp inside refrigerator continues to 4°C and monitor for problems.

Reviewed by: Janice Smith Office Mgr. Date: 6/20/2009
## Sofia Analyzer Calibration Check

**Calibration Check Frequency:** Every 30 days  
**Sofia Analyzer #:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Calibration Cassette Number</th>
<th>Calibration Check Result (Pass / Fail)</th>
<th>Tech</th>
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**Corrective Action Documentation:**

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<th>Problem</th>
<th>Resolution</th>
<th>Tech</th>
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**SOFA SARS ANTIGEN FIA, KIT QC (EXTERNAL QC)**

**Kit:** Sofia SARS Antigen FIA Kit  
**Manufacturer:** Quidel Corporation

**EXPECTED RESULTS:**

<table>
<thead>
<tr>
<th>Lot #</th>
<th>Exp. Date</th>
<th>Receive Date</th>
<th>Positive Control</th>
<th>Negative Control</th>
<th>Date</th>
<th>Tech</th>
<th>Reviewed by Date/Initial</th>
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<td>Negative QC</td>
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Reviewed by: ___________________________  Data: ___________________________
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
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.
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
References

Questions?