COVID-19 Certification, Testing, and Result Reporting

November 8, 2021

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Welcome

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Presentation Overview

This presentation will cover:
- The CLIA Certification Process
- Performing and Understanding Testing
- Reporting of COVID-19 Results

November 8, 2021

Clinical Laboratory Improvement Amendment (CLIA) Certification Process

What is CLIA?

- Federal program for certification of facilities performing lab testing.

- All facilities that perform lab testing and use the results for diagnosis, assessment, and/or treatment of individuals require a CLIA certificate.

- The Wisconsin Department of Health Services (DHS) has an agreement with the Center for Medicare and Medicaid Services (CMS) to oversee the certification and regulation of lab testing in Wisconsin.

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Do you need a CLIA Certificate?

- **Do you need a CLIA certificate if you will be performing COVID-19 rapid antigen or molecular testing?** YES.

- **Do you need a CLIA certificate if you contract with a vendor or company that will be performing COVID-19 rapid antigen or molecular testing for your business?** NO. But the company performing the testing must have a CLIA certificate.

- **Do you need a CLIA certificate if you will be collecting specimens only and sending to a laboratory for COVID-19 testing?** NO.

If you have questions on whether or not you need a CLIA certificate, please email DHSDQACLIA@wi.gov.

CLIA Certificate Types

- **4 Types**: Certificate of Waiver, Provider Performed Microscopy, Certificate of Compliance, Certificate of Accreditation.

- **Certificate of Waiver (CoW)**: Any test system that has been classified by the Food and Drug Administration (FDA) as a "waived" complexity level must obtain a CoW.

- Most rapid point of care COVID-19 antigen tests are categorized at the waived complexity level and will require a federal CoW.

- For questions regarding a higher complexity level of testing outside the scope of a CoW, please email DHSDQACLIA@wi.gov.

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Application Process: Review Laboratory Quick Start Guide

A federal CMS-116 CLIA application must be submitted to the state agency. The Center for Medicare and Medicaid Services (CMS) has federal oversight of the CLIA program and the following link is a CMS Laboratory Quick Start Guidance Document explaining the application process: https://www.cms.gov/files/document/laboratory-quick-start-guide-cms-clia-certification.pdf

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Application Process: Complete CMS-116 CLIA Application

The CMS-116 CLIA Application (for providers without an existing CLIA certificate) is a 10-page document and includes instructions on how to complete the application: https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf.

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Application Process: Submit CLIA Application

- Submit completed application or questions to the CLIA section at DHSDQACLIA@wi.gov.

- Once approved, a federal CLIA number is assigned and an email of confirmation is sent to the provider.

- Providers may begin testing once assigned a CLIA number.

- NOTE: Application typically take 1-3 business days to process.

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CLIA Certificate

- Approximately 3-4 weeks after your CLIA number assignment, you will receive an invoice from CMS in the amount of $180. Failure to pay the invoice will result in the termination of the CLIA certificate.

- Submit payment directly to CMS or online at Pay.Gov: https://www.pay.gov/public/form/start/55598674

- The CLIA certificate is good for 2 years and CMS will send a renewal invoice 6 months prior to the expiration date of a certificate.

# Federal Testing Requirements for Waived Complexity Level COVID-19 Testing

- Follow the manufacturer's package insert instructions in their entirety. Failure to do so may result in testing errors and false negative or positive results.

- Report all negative and positive COVID-19 results to state and federal authorities.

CLIA Certificate Changes

- Providers are required to report the following to DHS within 30 days of the following changes:
  - Ownership
  - Name
  - Location
  - Director
- Change requests must be submitted in written format. Email DHSDQACLIA@wi.gov with certificate changes.

Testing Resource for the BinaxNOW COVID-19 Card Antigen Test: "Ready, Set, Test" Booklet

- "Ready, Set, Test" booklet for Waived Testing: https://www.cdc.gov/clia/docs/waived-tests/ready-set-test-booklet.pdf
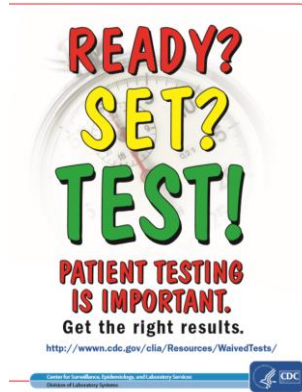
Recording, Reporting, Retaining Results

- **Record** results in a patient test log or other electronic documentation system. (Refer to Appendix C of the "Ready, Set, Test" booklet for examples.)

- Federal regulations require **reporting** of all negative and positive results to the federal government. One way to meet this requirement is through WLR (Web-based Laboratory Reporting) through the Wisconsin State Laboratory of Hygiene.

- All test records such as QC and patient testing records should be **retained** for a minimum of two years and easily retrievable. Records should include kit lot numbers, dates received and used, expiration dates, QC and patient results, test system failures, troubleshooting documentation, test kit or product recall notices, and personnel training records.

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Facility: Dr. Smith's Office

Location: 123 Main Street, Atlanta, GA 55555

Results Log with QC – Qualitative Test

**Test Name:** XYZ Strep antigen

	Date	Sample ID / Patient ID	Test Result	Initials	Test Lot number / Test Exp. Date	QC Lot / Exp Date	Positive Control Results	Negative Control Results
1	5/5/2015	5-05-20 / Tom Jones	NEG	SH	Bd-0679/ 11-30-2015	108-OCB / 9-30-15	POS	NEG
2	5/6/2015	5-05-22 / Mattie Dunn	NEG	CO	Bd-0679/ 11-30-2015	108-OCB / 9-30-15	POS	NEG
3								
4								
5								
6								
7								
8								
9								
10								

COMMON DISINFECTANTS AND ANTISEPTICS

Note: Any mention of trade names is for identification purposes only and is not intended as an endorsement. Proprietary disinfectant products should be used in accordance with the manufacturer's instructions for concentration, contact time, or other conditions of use.

Selected EPA-registered disinfectants: A list of EPA's registered sterilizers, tuberculocides, and antimicrobial products against certain bacteria and viruses can be found at: http://www.epa.gov/oppad001/chemregindex.htm

1. **Chlorine compounds** are powerful disinfectants that are inexpensive and easy to obtain. Sodium hypochlorite or household chlorine bleach solutions possess intermediate-level disinfectant properties. For maximum potency, the working solution should be prepared fresh at the time of use or daily as needed, but studies show that weekly preparations work too. A 10% bleach solution is also referred to as 1/10, 1:10 or 5,000 ppm bleach solution. The directions for preparation are:
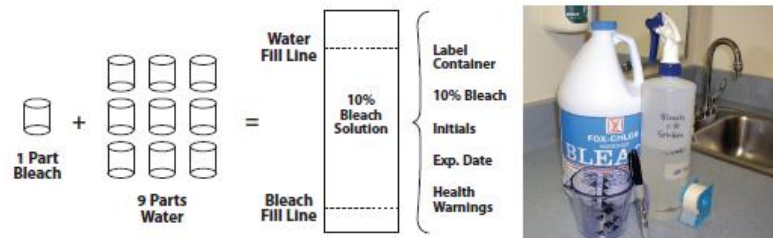
Note: bleach will corrode some equipment. Refer to manufacturer's recommendations for cleaning and disinfecting procedures.

2. **Alcohols** are considered intermediate level disinfectants. Alcohol solutions are often used as a skin antiseptic. Alcohols, such as isopropyl (rubbing) alcohol, are well suited to rapidly kill bacteria on the skin surface in preparation for fingerstick or venipuncture.

3. **Commercial Products.** The EPA provides a list of registered commercial products that are effective against certain bacteria and viruses. Examples are 'Lysol' (cresol and soap solution) and 'Stericol' (xylenol-rich cresylic acid and soap solution)

Additional CLIA Resources

- Center for Disease Control (CDC) Guidance on COVID-19 Testing: [Guidance for SARS-CoV-2 Point-of-Care and Rapid Testing | CDC](#)

- Instructions to set-up a Web-Based Laboratory Reporting (WLR) account: [Web-Based Laboratory Reporting (wisconsin.gov)](#)

- Link to order COVID-19 testing supplies through the State of Wisconsin (eligibility criteria apply): [COVID-19 (wi.gov)](#)

- Ready-Set-Test: https://www.cdc.gov/clia/docs/waived-tests/ready-set-test-booklet.pdf

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Performing and Reporting SARS-CoV-2 Rapid Testing

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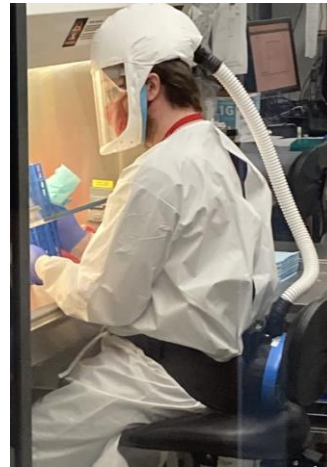STOP
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Patient feels ill

- They should immediately be isolated from others.
- Instruct them to wear a mask and get tested.

At the testing site

- Collection staff should wear appropriate personal protective equipment (PPE).
  - Safety glasses or face shield
  - N95 Mask or PAPR
  - Gloves
  - Gown or clothes cover

  *Safety Tip: Don't get infected by your patients!

- https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html#:~:text=For%20healthcare%20providers%20collecting%20specimens,respirator%20is%20not%20available)%2C%20eye
- https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html

Change your PPE

- Gloves should be changed between each patient.
- Full PPE should be changed at least each week.
- Also change PPE as needed:
  - If you get sneezed or coughed on.
  - If you spill or get test material on you.
  - If you have any other contamination concerns.

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Have a testing station

- Designate a testing table.

- Keep supplies on hand.
  - Additional PPE, especially gloves
  - Test kits
  - Cleaning supplies

- Record keeping resources
  - Smart phone OR Computer

- Timers

- Biohazardous waste container

Waste Disposal

- What is considered Biohazardous waste?
    - Anything that may contain infectious material
    - Swabs, testing materials, used kits, contaminated PPE

- How do you dispose of Biohazardous waste?
    - Refer to DOT procedures on transport and disposal.
    - Find hazardous waste disposal companies in your area.

Safety Tip: Don't infect your janitors!

DOT Safety Advisory Notice for transport of COVID samples:
https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2020-06/UN3373%20COVID%2019%20Safety%20Advisory.pdf

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Start a patient record

- Full name and date of birth*
- Date and time of collection*
- Address and contact information
- Other requested information from the Department of Health and Human Services (HHS)

- Unique patient number
- Unique specimen number
- Email address
- Phone number

SpecimenNo	DateRecd	DateCollected	SpecimenSource	PatientLastName	PatientFirstName	MI	DOB	Sex	Ethnicity	Race	PtStreetAddress	PatientCity	PtState	PtZip	PtTeleph
20VR005555	6/13/2019	6/10/2019	NP	ZZTEST	Dancer	J	5/1/2018	M	Not Hispanic or Latino	W	1234 Main St	Madison	WI	53706	608-555-5
20MP008888	6/13/2019	6/9/2019	Sputum	ZZTEST	Cupid	K	2/3/2017	F	Hispanic or Latino	B	1234 Main St	Madison	WI	53706	608-555-5
20TX007777	6/13/2019	6/5/2019	Blood, Venous	ZZTEST	Donnor	L	7/30/2016	M	Not Hispanic or Latino	A	1234 Main St	Madison	WI	53706	608-555-5

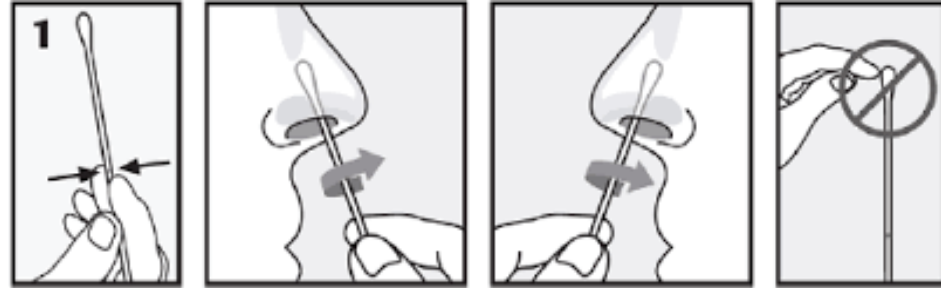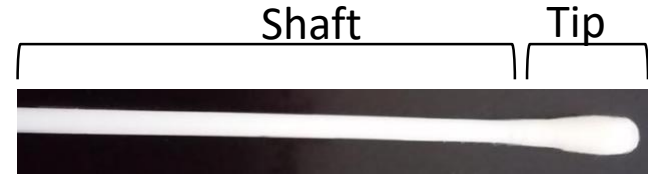Keep records for at least 2 years!

*Required

Swab the patient

Shaft | Tip

Nasal Swab Instructions for rapid tests:

1. Carefully remove swab from package.

2. Hold swab at the halfway point.

3. Insert swab just past the tip.

4. Rub the swab along the inner walls of the nostril **5 times.**

5. Using the same swab, do the **other** nostril.

6. Test swab immediately.

Note:
- Do not touch the tip before or after collection.
- Do not set the swab down on a surface.
- Do not put the swab back in the package.
- Do not force the swab if there is resistance.

https://www.youtube.com/watch?v=EjYajvm9zPw
https://www.youtube.com/watch?v=5HIXpiZnP_c

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Performing testing

- Do not deviate from the instructions.
- Set timers to ensure proper time is followed.
- Label each test to ensure there are no mix-ups.
- Record results immediately.
- Run control samples (+/- with each new shipment or lot).
- Discard used kit and swab in a biohazardous waste container.
- Privately tell the patient their results.
- Produce a report to hand to, mail, or email to patients.

Pro tip: If doing rapid testing, have the patient wait for the results!

Clean your work area

- Use bleach-based spray and paper towels.
- Clean at the end of each day (minimum).
- Clean after a spill, dropped swab, sneeze, etc.
- Consider a quick wipe down between each patient.
- Wash your hands regularly.

Report your results

- Reporting of ALL COVID-19 testing to public health is **required.**
  - All results on Wisconsin patients needs to be reported to the State of Wisconsin.
  - Results are not forwarded to the state by HHS.
- Report at least **every day** you perform testing.

Report your results

Methods available

- Web-based Lab Reporting (WLR)
  - Spreadsheet upload at the end of each day
  - Sign-up at: http://www.slh.wisc.edu/wlr-request/
- Electronic Lab Reporting (ELR)
  - Only for high volume testing sites

- Email the Wisconsin State Laboratory of Hygiene with questions: CDDELR@slh.wisc.edu
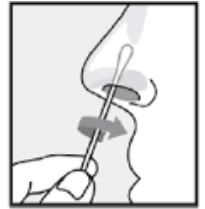
Determine if they need follow-up testing

- Some patients will benefit from confirmatory testing with a lab-based molecular test. Refer to current state guidance.
  - Rapid tests are at greater risk for false positives when testing a population with low rates of disease (<5%).
  - They are at greater risk for false negatives in symptomatic people with a high prevalence population (>10%).

Recollect for lab-based testing (if needed)

- Use a collection kit specific for your laboratory.

- Label the kit with name, DOB, and collection time/date.

- Using the included (new) swab, re-swab the patient the same as before.
  - Insert just past the flocked end.
  - Swirl 5 times.
  - Repeat on other nostril.

- Place swab in tube of provided transport media swirling and dabbing to shake off the collected material.

- Secure the lid of the tube and seal in the transport bag.

Swab snapping instructions:
http://www.slh.wisc.edu/wp-content/uploads/2020/08/Flier-Breaking-the-collected-swab-into-transport-media-Final.pdf

Transport specimen to the lab

- Package the specimen as Category B.
  - Don't forget to add frozen cold packs!

- Order courier pick-up for delivery to the lab.

Packaging instructions: http://www.slh.wisc.edu/wp-content/uploads/2020/08/200730_Packaging-and-Shipping-instructions.pdf

Good Practices

- Read the package insert and practice testing prior to testing real patients.

- Test control swabs to ensure the kits are working correctly.

- Don't mix components of one kit with another.

- Store at appropriate temperature and avoid temperature extremes.

- Keep good records on training, QC, and test results.

Checklist of items needed

❑ Timers

❑ Tables

❑ Cleaning supplies (bleach spray and paper towels)

❑ Hand soap

❑ Reporting device (phone app or computer)

❑ PPE

❑ Biohazardous waste system

Additional Resources

- CDC Safety information: https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

- How to do a nasal swab video: https://www.youtube.com/watch?v=AqvIoK3UuMo

- Swab snapping instructions: http://www.slh.wisc.edu/wp-content/uploads/2020/08/Flier-Breaking-the-collected-swab-into-transport-media-Final.pdf

- Cat B Packaging instructions: http://www.slh.wisc.edu/wp-content/uploads/2020/08/200730_Packaging-and-Shipping-instructions.pdf

- WLR Reporting sign-up: http://www.slh.wisc.edu/wlr-request/

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