NM School Laboratory Standard Operating Procedures: CLIA Certificate of Waiver Umbrella Program

through the

Four Corners Regional Education Cooperative #1

Version: 8/3/2022

http://NMREC1.org
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General Policies

This Laboratory School CLIA Certificate of Waiver Standard Operating Procedures (SOP) is to be followed by any school or school district participating in the Four Corners REC-1 CLIA Certificate of Waiver COVID-19 Point of Care testing in schools.

This SOP follows federal Clinical Laboratory Improvement Amendments (CLIA) regulations and provides specific direction to ensure consistency and quality of testing. The following information is included as per CLIA regulations (Subpart K, 493.1211):

- specimen collection, processing, and reporting criteria requirements
- step-by-step performance of procedures, including test procedures and interpretation of results
- criteria for specimen storage and preservation to ensure specimen integrity until testing is completed
- preparation and use of solutions, controls, and other materials used in COVID -19 Point of Care testing
- The system for reporting patient results including, when appropriate, the protocol for reporting critical values
- Disposal of biohazard waste per state and federal guidelines
- Control procedures to include remedial action to be taken when control results fail to meet the lab's criteria for acceptability

Manufacturer's package inserts or operator manuals may be used to meet these requirements; any additional information not included by the manufacturer is included in the SOP. B It is the responsibility of all school personnel involved with the school's laboratory operations to review, understand, and follow these procedures and to seek clarification when necessary.

CLIA: Clinical Laboratory Improvement Amendments

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). The Division of Clinical Laboratory Improvement & Quality has the responsibility for implementing the CLIA Program. The objective of CLIA is to ensure quality laboratory testing. To learn more, go to:https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html. You may also contact the NM State CLIA Agency or the NM Health Facility Licensing & Certification Bureau in the NM Bank ofthe West building at 5301 Central Avenue NW, Suite 400, Albuquerque, NM 87108. Phone number is 505- 222-8684 and FAX: (505) 845834. Please contact Julie Aragon.

Internet: http://dhi.health.state.nm.us/index.php .

The school laboratory space must include:

- adequate space for testing
- proper ventilation, lighting and hand washing/eye washing per Occupational Safety and Health Administration (OSHA) standards, and local and state building codes
- utilities necessary to permit proper test conditions
- posted safety precautions
- room temperatures must meet requirements for testing and storage per manufacturer's guidelines with temperature ranges documented twice daily on the temperature log provided
- laboratory equipment, specimens, and documents to be under appropriate control unauthorized personnel
- COVID -19 tests to be maintained in accordance with manufacturer's instructions
- surfaces in the laboratory to be cleaned and logged on the hard surface disinfection log provided
- current REC-1 CLIA of Waiver posted in each school laboratory
- Safety Data Sheets (SDS) available in a centralized location, accessible to all personnel. All SDS must be kept together in a notebook for quick and easy reference or be easily accessible online. SDS's should be regularly reviewed with staff
- use Environmental Protection Agency (EPA) approved agents or appropriate bleach solutions for disinfecting. Follow manufacturer's recommendations for use. **Note**: Bleach loses disinfecting effectiveness within 24 hours when diluted with water; therefore, bleach disinfecting solutions should be mixed as needed. Six months is the recommended shelf life for a bottle of undiluted bleach if kept between 50ºF-70ºF, once opened
- all EPA approved disinfecting agents should have date opened and stored in a location that will not leach into other products and are stored safely for student/staff protection

Evaluation site visits will be conducted by Four Corners REC-1 personnel to ensure CLIA compliance, and as needed

COVID -19 Test Kit Supply and Storage Management

It is important to manage the Point of Care COVID -19 test kits per the following criteria:

- maintain storage conditions as per manufacture's package insert
- lab temperatures to be monitored twice daily (except for weekends and holidays) where test kits are stored
- keep package inserts for three years. Label each insert with initials, in use/open date, and a discontinued/discard date
- ensure that all labels used on testing kits include:
  - receipt date
  - preparation date/date opened and initials of person preparing/opening
  - expiration date

Do not write directly on plastic containers due to possibility of leaching of ink into the solution

Complaints

Complaints are be documented and reported immediately to REC-1. The REC-1 has the right to conduct a complaint investigation. The follow is to be included in documentation:

- Name of complainant.
- Name of the test.
- Date of the test.
- Specific nature of the problem.
- Why the result was different than expected.
- Location of the school lab where the test was done.
- Review the incident with the personnel and documented with resolution to the incident.
- When the complaint is validated, a Lab Improvement Report must be completed and placed in school's laboratory QC Manual

Roles and Responsibilities

The school laboratory is to have a designated coordinator who is responsible for the overall administration of the laboratory. REC-1 is considered the school or district's CLIA Certificate of Waiver laboratory director since the CLIA Certificate of Waiver has been issued to REC-1.

The laboratory director responsibilities:

- reviewing duties of the school laboratory coordinator and testing personnel if applicable.
- participating in annual or as needed review of the SOP manual
- providing consultation to schools upon request.
- conducting onsite and virtual site reviews
- skills Checklist for the school laboratory coordinator for COVID-19 Point of Care test listed under CLIA Certificate of Waiver and used by school laboratory
- conducting a school laboratory checklist prior to Point of Care COVID-19 testing and ongoing as needed
- sending the CLIA of Waiver to the school or school districts laboratory coordinator for posting
- attending CLIA Certificate of Waiver meetings and professional development offerings and meetings as needed

School Laboratory Coordinator's Responsibilities:

School laboratory coordinators will provide training for all employees that will be testing and assist with ongoing training and skills evaluations. .If the Laboratory Coordinator position is vacant, the responsibility to ensure training falls up the chain of command. Responsibilities include:

- ensuring all school lab room staff can access the SOP manual
- ensuring quality laboratory services and corrective action when problems occur, by scheduling site reviews and performing review of the procedures (SOP) manual
- ensuring all paperwork is completed correctly and documentation is maintained
- ensuring and documenting that Point of Care COVID-19 kits are authorized to be used under REC-1 CLIA Certificate of Waiver and are acceptable upon receipt. If not, contact the appropriate personnel and document any issues
- completing QA monitoring requirements per policy and procedure
- reviewing all quality control logs to ensure that correct lot numbers and expiration dates are on the QC log sheets. This activity requires comparing lot numbers and expiration dates from control materials, test strips, test kits, and reagents. All control materials, test kits, must be labeled with the opened date, the expiration date, and the initials of person opening the product. If controls are needed: Discontinue any tests for which there are no control materials until they are available
- reviewing Lab Logs (See Appendix) to ensure tests have results; document any missing results
- maintaining lab supplies and equipment maintenance and calibration records
- ensure that reagents and solutions labeled with identity, titer or concentration, storage requirements, and receipt, opening, and expiration dates. Reagents and solutions must not be used if deteriorated or outdated.
- ensuring ambient room temperature is recorded twice daily

- training new personnel and assisting with ongoing training.
- maintaining files for two years plus the current year as per CLIA Certificate of Waiver requirements
- conducting site review monthly, and record results using NM Schools Laboratory Skills Checklist.
- following the appropriate laboratory procedures for:
  - specimen handling
  - specimen processing
  - results reporting and documentation (including in the laboratory log, as well as positive/negative results reporting to protocol and the student's school health record record).

CLIA Waived Point of Care COVID-19Testing Personnel

All school personnel conducting COVID-19 Point of Care tests, and reporting test results are responsible for:

- reviewing and completing any required trainings prior to performing any laboratory duties and are not to perform any procedure independently unless determined to be competent in the procedure.
- performing all laboratory procedures according to the NM School Lab SOP and manufacturer's directions
- performing only those tests where they have successfully completed training and competency testing and are authorized under the REC-1 CLIA Certificate of Waiver
- participating in all training or quality activities requested by the school's laboratory coordinator
- performing or checking QC procedures documentation and completion prior to testing
- monitoring testing materials for correct storage, including daily temperature checks if assigned or required
- communicating all laboratory questions and concerns to school laboratory coordinator
- observing infection control precautions during all student/staff care, specimen collection, and handling, and donning and doffing of PPE

School Laboratory Training

To ensure high-quality CLIA Waived Point of Care COVID-19 testing, staff must be familiar with the school or district Health and Safety Program, including "Infection Control of the Health Care Worker" Protocol and the Bloodborne Pathogens training, which must be reviewed and completed annually. Records of training, assessment, and educational documentation for each person covered by these procedures. All new personnel will complete competency testing prior to performing any testing or quality control monitoring.

All school personnel conducting COVID-19 Point of Care tests must attend training as requested and manufacturer's training for the product. Work in compliance with the NM School Laboratory SOP, OSHA safety program for health care workers and other relevant OSHA standards, rules, and regulations.

Safety

All school laboratory personnel shall:

- complete bloodborne pathogens trainings and review the NM Schools Standard Operating
- attend manufacturer's training, know manufacturer's procedures, and be skills evaluated by the school's laboratory coordinator prior to performing COVID-19 test
- review the personal protective equipment (PPE) fact sheet as it relates to the OSHA Bloodborne Pathogens Standard: https://www.osha.gov/OshDoc/data_BloodborneFacts/bbfact03.pdf
- review school or school district's procedures for post exposure and treatment, including the workers compensation process prior to completing laboratory procedures
- identify where local Safety Data Sheets (SDS) are kept in the local area.
- review OSHA definitions and guidance around the Bloodborne Pathogens Standard, Universal Precautions and Standard Precautions: https://www.osha.gov/SLTC/bloodbornepathogens/worker_protections.html
- demonstrate correct use of all necessary PPE prior to performing any procedures with the potential for exposure to potentially infectious materials.
- review procedures for disposal of hazardous waste
- decontaminate work surfaces and immediately after a spill per protocol.
- dispose of all infectious waste per protocol
- no eating, drinking, smoking, handling contact lenses, and applying cosmetics in the school laboratory area
- dress appropriately! Wear close-toed shoes, keep hair tied back and ensure you have appropriate PPE available
- wash your hands after handling infectious materials and upon leaving the area.
- follow procedures so that splashes or aerosols will be minimized. Dispose of all BinaxNOW cards as biohazard waste and sharp items promptly in puncture-proof containers for disposal

Safety first! If you have a safety concern, report it immediately through your chain of command. Safety concerns cannot be addressed unless they are reported. NO CONCERN IS TOO SMALL TO REPORT!

Specimen Collection

Specimen collection is to be followed as outlined in the manufacturer's COVID-19 test procedure. General issues to consider include:

- student/staff identification and verification- prior to performing any laboratory procedures, all staff must ask the student/staff for their name/Date of Birth (DOB) to confirm the correct identity.
- informed consent - All students and staff shall have an opportunity to review the manufacturer's patient information sheet prior to giving obtain written consent prior to any testing
- the minimum consent requires personnel to:
  - provide an explanation of the test, including its purpose, potential uses, limitations, and the meaning of its results
  - describe the procedure that will be used and any risks.
  - provide the student/staff member an opportunity to have all their questions answered and to decline testing. If a student/staff member delays or declines testing, provide information about the possible risks associated with the delay or declination.

Specimens are to be labeled at the site of testing and labeled only with non-identifying number (e.g., the number in the lab log) and do not label with name and date of birth as these will be disposed of in waste containers.

Forms must be completed legibly with all information by the testing laboratory (school site) with results provided verbally, and in writing (directly or fax and may be released to:

- the student's parent or legal guardian, or the student if the student is 18 years of age or older.
- staff members
- to another healthcare provider involved in the care of the client (a signed release is preferred but not required
- to another party with a signed release, or as otherwise required by law (e.g., in response to a subpoena after review by the administration

Known or potential breaches of confidentiality, including the inappropriate release of results, must be reported to the local privacy officer within REC-1 and the school or district the same day of acknowledgement.

Results for an individual are not provided to partners or contacts of cases of communicable disease without the consent of the individual or the student's legal guardian.

NM Schools Laboratory Test Result Reporting

All schools conducting Point of Care COVID-19 test must be set up to report through Simple Report. Training is needed first before portal is granted.

Test results are to be reported when they are available. Reporting mechanisms must comply with CLIA, HIPAA, and any NM DOH program policies and procedures. Test reports must be accurate. Normal ranges are identified according to test procedure or clinic protocols. Results must be documented accurately: Results should be documented in

- the student's health record.
- laboratory Logs

Copies of the Laboratory Logs are to be maintained for at least three years from date of testing in each school laboratory.

Quality Assurance

Quality assurance is maintained by:

- The SOP is reviewed as needed All school laboratory personnel must sign the NM Schools Laboratory SOP as documentation of their knowledge and acceptance of the protocols initially and annually. Use Authorized Testing Personnel Summary.
- School staff must not test student/staff specimens or perform quality control testing until they have read the SOP, completed training, and are verified competent.
- Maintain discontinued protocols (including those discontinued due to revision during the interim period) for two years plus the current year, and have a discontinued date clearly indicated
- Document routine and as needed QA monitoring of school laboratory sites for ambient room temperature monitoring, staff proficiency testing, use of internal and external controls, documenting of test results, and reporting of test results per protocol, and any corrective action taken as needed. Use the BinaxNOW COVID -19 Testing Checklist. Monthly lab audits are to be completed.
- Review and observe staff conducting infection control precautions during all testing of students/staff, specimen collection, and handling.

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). The Division of Clinical Laboratory Improvement & Quality has the responsibility for implementing the CLIA Program. The objective of CLIA is to ensure quality laboratory testing.

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html

New Mexico State CLIA Agency:

Health Facility Licensing & Certification Bureau Bank of the West Building 5301 Central Avenue NW, Suite 400, Albuquerque, NM 87108 (505) 222-8646 FAX: (505) 841-5834 Contact: Julie Aragon

Internet: http://dhi.health.state.nm.us/index.php .

All school laboratories will maintain and post a CLIA Certificate for each school laboratory site.

Personal Protective Equipment (PPE)

OSHA Fact Sheet on PPE: https://www.osha.gov/OshDoc/data_BloodborneFacts/bbfact03.pdf

PPE is designed to protect employees from serious workplace injuries or illnesses resulting from contact with chemical, radiological, physical, electrical, mechanical, or other workplace hazards. PPE such as protective eye wear and masks are available to all employees who may perform duties with exposure to potentially infectious materials.

Primary Barriers:

items related to face protection, eye protection goggles or face shield, medical grade masks, disposable gowns, and gloves.

Secondary Barriers:

- Each laboratory should contain a sink for washing hands.
- Each laboratory should contain an eye wash station or kit.
- The laboratory should be designed for easy cleaning.
- If the laboratory has a window that opens, it should be fitted with a fly screen. you have been exposed to a chemical or to potentially infectious materials, please notify the following individuals as soon as it is safe to do so (please review school's Health and Safety Manual or Policy).

If you have been exposed to potentially infectious materials, it is essential that you receive an immediate evaluation by a licensed professional with experience in treating occupational exposures to potentially infectious materials.

Always notify, as soon as possible, your assigned supervisor about the exposure to arrange for work coverage while you go for immediate evaluation.

School Administrator: _____

Phone # _____

As soon as possible (may be after your medical evaluation and treatment), fill out a first notice of accident report (see your supervisor or human resources staff for assistance) and work with your human resources staff to ensure all workers compensation paperwork is completed in a timely and complete manner.

Retain copies of all medical treatment and receipts for your records.

APPENDICES

1. Staff Training Log
2. Product Insert
3. NM Schools Laboratory Quality Improvement Form
4. Room Temperature Monitoring Log
5. NM Schools Laboratory Results Log
6. NM schools Laboratory Hard Surface Disinfection Log
7. NM Laboratory Quality Assurance Monitoring Form
8. NM Schools COVID -19 Test Quality Control Log
9. NM Schools Laboratory Test Kit Inventory Management Log
10. COVID-19 Testing Checklist
11. BinaxNOW COVID-19 Test Collection Skills Checklist
12. Sample Consent form for Covid-19 antigen testing
13. Sequence for Putting on Personal Protective Equipment (PPE)
14. Sequence for Removing Personal Protective Equipment (PPE)
15. Guidance for putting on / taking off PPE
16. OSHA Fact Sheet
17. Hand Washing Sign
18. No Food or Drink Sign
19. Biohazard Sign
20. What is a CLIA
21. Waste Disposal Recommendations

Staff Training Log

This is to verify that personnel responsible for conducting the

_____ test at

_____(school)

have been thoroughly in-serviced on the test and the test procedure. This has included:

- Review of the package insert
- Demonstration of the product assay
- Successful performance of the assays and result reporting

Names of the personnel who have been trained and are responsible for reporting patient results:

PRINT NAME	SIGNATURE	DATE

Signature(s) of responsible personnel for testing:

_____ _____

SIGNATURE DATE

_____ _____

SIGNATURE DATE

_____ _____

TRAINER DATE

NM Schools Laboratory Quality Improvement Report Form

Date: _____

Employee Reporting Incident _____

Laboratory (site): _____

1. Briefly describe the incident, dates, times, etc.:

2. Describe what corrective and preventive actions are being taken (include names, dates, etc.):

Laboratory	Dat
Laboratory Director/Medical	Dat

*It is the responsibility of the School's Laboratory Coordinator to maintain copies

Room Temperature Monitoring Log

Month/Year:	Room Temperature Monitoring Log for the Lab Room	Days 1-15

Day of the Month:		1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Maximum Temp																															
Minimum Temp																															
Staff Initials:																															
Room Temperature	°F	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Too Warm	>80°																														
	79°																														
	78°																														
Acceptable Range for the Lab Room is 68°F to 77°F.	77°																														
	76°																														
	75°																														
	74°																														
	73°																														
	72°																														
	71°																														
	70°																														
	69°																														
	68°																														
Too Cold	67°																														
	66°																														
	<65°																														

Instructions

1. Record the temperature with an **X** twice every workday. Document with your initials
2. For out of range temperatures, adjust the temperature controls and document the adjustment on the log. Recheck the temperature one hour later and record. If not in range at that point needs to be repaired; discontinue use.
3. Keep this log for 2 years.

Notes: _____

Month/Year:

Room Temperature Monitoring Log for the Lab Room

Days 16-31

Day of the Month:		16		17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
Maximum Temp																																	
Minimum Temp																																	
Staff Initials:																																	
Room Temperature	°F	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
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	66°																																
	<65°																																

Instructions

1. Record the temperature with an **X** twice every workday. Document with your initials
2. For out of range temperatures, adjust the temperature controls and document the adjustment on the log. Recheck the temperature one hour later and record. If not in range at that point needs to be repaired; discontinue use.
3. Keep this log for 2 years.

Notes: _____

NM Schools Laboratory Results Log

Laboratory/CLIA#: **Lab Address:** **Lab Phone #:** **Collection Date:**

Client Name	Address	DOB	Tele	Sex	Ethnicity - Race	Test	Result	Client Notified	Notes If positive, name/address/telephone of school/employer
		/ /		□ Male □ Female □ Other □ Unknown	□ Hisp/Lat □ Not Hisp/Lat □ Unknown □ Declined □ Asian □ AI/AK □ Black/AA □ Nat Hawaiian/PI □ White □ Unknown □ Declined	√ BinaxNOW	□ Pos □ Neg □ Invalid	□ Yes □ No	Symptoms: □ Yes □ No
		/ /		□ Male □ Female □ Other □ Unknown	□ Hisp/Lat □ Not Hisp/Lat □ Unknown □ Declined □ Asian □ AI/AK □ Black/AA □ Nat Hawaiian/PI □ White □ Unknown □ Declined	√ BinaxNOW	□ Pos □ Neg □ Invalid	□ Yes □ No	Symptoms: □ Yes □ No
		/ /		□ Male □ Female □ Other □ Unknown	□ Hisp/Lat □ Not Hisp/Lat □ Unknown □ Declined □ Asian □ AI/AK □ Black/AA □ Nat Hawaiian/PI □ White □ Unknown □ Declined	√ BinaxNOW	□ Pos □ Neg □ Invalid	□ Yes □ No	Symptoms: □ Yes □ No
		/ /		□ Male □ Female □ Other □ Unknown	□ Hisp/Lat □ Not Hisp/Lat □ Unknown □ Declined □ Asian □ AI/AK □ Black/AA □ Nat Hawaiian/PI □ White □ Unknown □ Declined	√ BinaxNOW	□ Pos □ Neg □ Invalid	□ Yes □ No	Symptoms: □ Yes □ No

*AI/AK = American Indian/Alaskan native, AA = African American, PI = Pacific Islander, LoSTS = Loss of Sense of Taste or Smell

Use additional forms for each day as needed.

NM Schools Laboratory Hard Surface Disinfection Log

Lab location: _____

Solution: _____

Month / Year: _____

	Staff signature		Staff signature
1		17	
2		18	
3		19	
4		20	
5		21	
6		22	
7		23	
8		24	
9		25	
10		26	
11		27	
12		28	
13		29	
14		30	
15		31	
16			

Each day will have an entry. Please mark services

"W" for weekends
"H" for holidays
"N" for no

NM Schools Laboratory Quality Assurance Monitoring Form

Location:_____ Year: _____

QA Monitor is performed monthly. If any of the verifications are found to be unacceptable, complete the NM Schools Laboratory Quality Improvement Report

√ = Acceptable N = Not Acceptable N/A= Not Applicable	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
QC Log												
1. Verify the correct lot #'s, expiration dates, date performed, and initials of the analyst are recorded on the Quality Control Log												
2. Verify controls were performed prior to patient testing and/or according to procedural requirements												
3. Verify the reported results are within expected range												
4. Verify Daily Ambient Temperature Logs Maintained												
√ = Acceptable N = Not Acceptable N/A= Not Applicable	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC

Lab Coordinator Review:

1st Quarter: _____ **Date:** _____

2nd Quarter: _____ Date: _____

3rd Quarter: _____ **Date:** _____

4th Quarter: _____ **Date:** _____

CLIA CoW Laboratory Director Review:

1st Half _____ **Date:** _____

2nd Half _____ **Date:** _____

NM Schools Quality Control Log

This form is to be used by the School Laboratory Coordinator for QA reviews

Lot number for TestBox Consistent with Documentation	Expiration Date of Test Box of Kits Documented	Date Box Opened Documented	Initial of personnel opened Documented	Date QA Control Performed for Lot Documented

NM Schools Laboratory Test Kit Inventory Management Log

Date Received Tests Kits	Number of Test Kits Received	Lot Number	Expiration Date	Room Temperature upon Storage

COVID-19 Testing Checklist

	Steps Needed	Compliance			Comments
	Administrative Duties				
	District/School:				
	Testing Coordinator:				
	Testers:				
1	Current Lab Standard Operating Procedure (SOP) accessible.	Yes	No	N/A*	
	Attended New Mexico Schools COVID-19 Testing (3):				
2	Process and Program Overview	Yes	No	N/A	
3	CLIA School Laboratory Training	Yes	No	N/A	
4	Reporting Requirements & BH Considerations	Yes	No	N/A	
5	Completed Bloodborne Pathogens Training	Yes	No	N/A	
6	Completed HIPPA Training	Yes	No	N/A	
7	Completed Donning and Doffing Training	Yes	No	N/A	
8	Completed Training for Eye Wash, Handwashing, Work Place Safety (optional)	Yes	No	N/A	
9	Parental Opt-In Consent Received for Distribution (*note: these must be received in writing in advance of test)	Yes	No	N/A	
10	Ambient air temperature verified, within range & correctly documented on Temperature Log twice daily.	Yes	No	N/A	
11	Skills Checkoff completed by Testing Coordinator	Yes	No	N/A	
	Laboratory Cleanliness and Organization				
12	Lab & lab equipment clean and organized.	Yes	No	N/A*	
	Personal Protective Equipment (PPE)				
13	Latex free Disposable Gloves	Yes	No	N/A*	
14	Disposable Gown	Yes	No	N/A*	
15	Surgical or Medical Grade Mask	Yes	No	N/A*	
16	Face Shield or Eye Goggles	Yes	No	N/A*	
17	Sink for handwashing	Yes	No	N/A	
18	Ambient Thermometer	Yes	No	N/A	
19	Trash receptacle with lid that is hands-free	Yes	No	N/A	
20	EYE Wash Station/Kits Present	Yes	No	N/A*	
21	Timer	Yes	No	N/A	
22	Biohazard bags/stickers	Yes	No	N/A	
23	Space allocated for CLIA Certificate (or if district has waiver send to SHA)	Yes	No	N/A	
24	Space allocated for Safety Precautions	Yes	No	N/A	
25	Log - Disinfecting	Yes	No	N/A	
26	Log - Testing	Yes	No	N/A	
27	Log - List of all personnel trained (return completed to SHA).	Yes	No	N/A	
28	Food and drink kept outside of the lab.	Yes	No	N/A*	

--CONTINUED ON NEXT PAGE--

QC Monitoring					
29	Testing performed at the appropriate intervals, within normal range, and the results documented on QC Log.	Yes	No	N/A	
Reports and Reporting					
30	Student/Staff results documented in Result Log.	Yes	No	N/A	
31	Quality Assurance Monitor completed monthly.	Yes	No	N/A	
32	Student/staff clinical records reviewed for completed lab results, and follow-up documentation based on # tests performed.	Yes	No	N/A	
33	Lab Improvement Report & Short-Term QC Monitor Form used correctly, reviewed for failed QC &/or test results, and all forms completed.	Yes	No	N/A	
Items to be sent after completion of the above					
34	Standing Order Received & Accessible	Yes	No	N/A	
35	All appropriate CAP/CLIA certificates available and posted.	Yes	No	N/A	

BinaxNOW COVID 19 Test Collection: Skills Checklist

Person Evaluated (Print please):_____Position:_____Evaluator:_____

		Date Demonstrated
EXTERNAL QUALITY CONTROL TESTING:		
A.	Open test card and lay flat.	
B.	Add 8 drops of the extraction reagent to the top hole of the swab well. Do not touch the card with the dropper tip while dispensing.	
C.	Insert the control swab into the bottom hole and firmly push upwards so that the swab tip is visible in the top hole.	
D.	Rotate (twirl) swab shaft 3 times clockwise to the right. Do not remove from swab.	
F.	Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read results in the window at 15 minutes after closing the card.	
G.	Correct control result should appear as a positive specimen and give two pink/purple colored lines. The external quality control should be performed with each new shipment received and once for each untrained operator.	
TEST PROCEDURE:		
1	Obtain health history of student or staff member for symptoms of COVID-19 in the past ten days and status of COVID-19 vaccination.	
2	Provide Abbott Fact Sheet for Patients & offer opportunity for questions.	
3	Ensure written consent has been obtained.	
4	Administer the test pursuant to the Product Insert and Procedure Card.	
5	Don appropriate PPE.	
6	Open test card and lay flat.	
7	Add 6 drops of the extraction reagent to the top hole of the swab well. Do not touch the card with the dropper tip while dispensing.	
8	Collect specimen by inserting nasal swab into the nostril using a gentle rotation, push the swab until resistance is met at the level of the turbinates' (less than one inch into the nostril). Rotate the swab 5 times or more against the nasal wall then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril.	
10	Insert sample into the bottom hole and firmly push upwards so that the swab tip is visible in the top hole of the swab well.	
11	Rotate (twirl) swab shaft 3 times clockwise to the right. Do not remove the swab.	
12	Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read results in the window 15 minutes after closing the card. (In order to ensure proper test performance, it is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 min).	
13	Doff PPE into trash and dispose of test into appropriate biohazard receptacle.	
14	Document the following:	
	1. Date, time, and location of test.	
	2. Name, address, date of birth, telephone number, sex, and race/ethnicity of person being tested.	
	3. Name, title, and professional license number (if applicable) of person administering the test.	
	4. Name of test and manufacturer lot number.	
	5. Results of the test.	
	6. Symptoms, if any; and, If positive, the name, address, and telephone number of the school or employer.	
15	Notify staff member or student's parent/legal guardian of test results.	
16	Submit required data to NM DOH per reporting requirements.	
17	For positive test results, immediately isolate the student or staff member and send home for isolation. Notify the school's designated COVID point of contact. Implement school contact tracing and appropriate control measures as published in latest version of NM PED NM School Toolkit.	

--CONTINUED ON NEXT PAGE--

RESULT INTERPRETATION:
A negative specimen will give a single pink/purple colored control line in the top half of the window, indicating a negative result. This control line means that the detection part of the test was done correctly, but no COVID-19 Antigen was detected.
A positive specimen will give two pink/purple colored lines. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint sample line. Any visible pink/purple colored line is positive.
If no lines or only sample line is seen: The assay is invalid. Invalid tests should be repeated.

_____ _____

Evaluator Signature Date

_____ _____

Signature of Person Evaluated Date

Sample Consent for COVID-19 Antigen Testing

Voluntary Testing Consent & Acknowledgment Form for _____

School / Site / District: _____

_____COVID-19 Point of Care test is an antigen test that detects the presence of the virus that causes a COVID-19 infection. Results from this test are usually available in about 15 minutes. There is no charge to you for these tests. Collecting the specimen for testing involves using a small swab into the front of the nose, not deep into the nose. This test is completely voluntary and will not be administered without signed consent. This test may be administered to your child at various times for various reasons. Both positive and negative results of this test will be reported to the New Mexico Department of Health so that it can begin contact tracing and other disease control measures if necessary. You will also be provided with the results of each test administered to your child.

Except as required by law, test results and testing information will be kept confidential by the school district and the NM Department of Health. NOTIFIABLE DISEASES OR CONDITIONS IN NEW MEXICO 7.4.3.13 NEW MEXICO ADMINISTRATIVE CODE. This code may be located at: NOTIFIABLE CONDITIONS IN NEW MEXICO (nmhealth.org)

Consent and Acknowledgment

Completing and signing this form serves as consent for this test to be performed on the named individual at various times as determined necessary by the school district. School personnel also acknowledge the above statements. Upon request, this completed and signed form should be provided to the appropriate school district personnel and will grant permission for trained school personnel to conduct multiple COVID -19 tests on your child throughout the school year. This consent may be revoked at any time.

Print name of person subject to testing: _____ DOB: _____

Print parent / guardian name: _____ Date: _____

Signature of parent / guardian: _____

School / District Use Only

Received by: _____ Date: _____

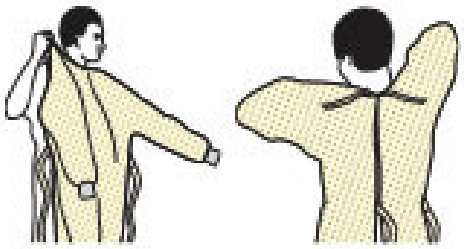
Place of test administration: _____on (Date) _____

SEQUENCE FOR PUTTING ON PERSONAL PROTECTIVE EQUIPMENT (PPE)

The type of PPE used will vary based on the level of precautions required, such as standard and contact, droplet or airborne infection isolation precautions. The procedure for putting on and removing PPE should be tailored to the specific type of PPE.

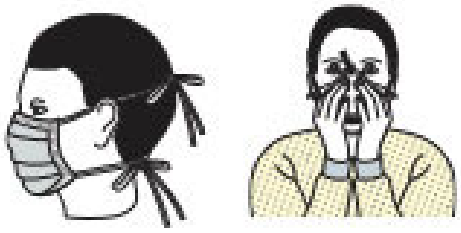
1. GOWN

- Fully cover torso from neck to knees, arms to end of wrists, and wrap around the back
- Fasten in back of neck and waist



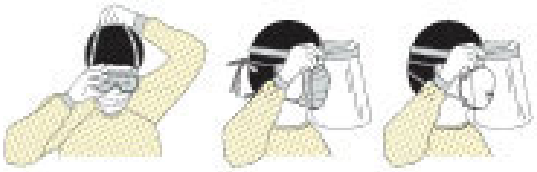
2. MASK OR RESPIRATOR

- Secure ties or elastic bands at middle of head and neck
- Fit flexible band to nose bridge
- Fit snug to face and below chin
- Fit-check respirator



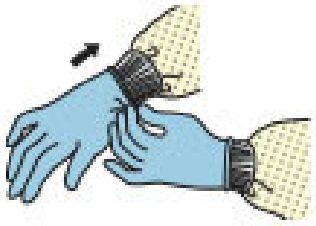
3. GOGGLES OR FACE SHIELD

- Place over face and eyes and adjust to fit



4. GLOVES

- Extend to cover wrist of isolation gown



USE SAFE WORK PRACTICES TO PROTECT YOURSELF AND LIMIT THE SPREAD OF CONTAMINATION

- Keep hands away from face
- Limit surfaces touched
- Change gloves when torn or heavily contaminated
- Perform hand hygiene

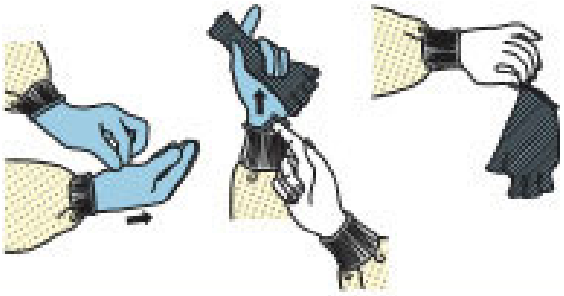
CDC

HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE)
EXAMPLE 1

There are a variety of ways to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. Here is one example. **Remove all PPE before exiting the patient room** except a respirator, if worn. Remove the respirator **after** leaving the patient room and closing the door. Remove PPE in the following sequence:

1. GLOVES

- Outside of gloves are contaminated!
- If your hands get contaminated during glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Using a gloved hand, grasp the palm area of the other gloved hand and peel off first glove
- Hold removed glove in gloved hand
- Slide fingers of ungloved hand under remaining glove at wrist and peel off second glove over first glove
- Discard gloves in a waste container



2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band or ear pieces
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a waste container

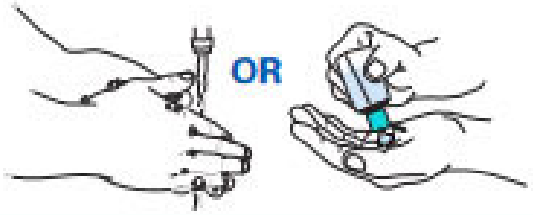
3. GOWN

- Gown front and sleeves are contaminated!
- If your hands get contaminated during gown removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Unfasten gown ties, taking care that sleeves don't contact your body when reaching for ties
- Pull gown away from neck and shoulders, touching inside of gown only
- Turn gown inside out
- Fold or roll into a bundle and discard in a waste container

4. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — DO NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in a waste container

5. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE



PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS BECOME CONTAMINATED AND IMMEDIATELY AFTER REMOVING ALL PPE

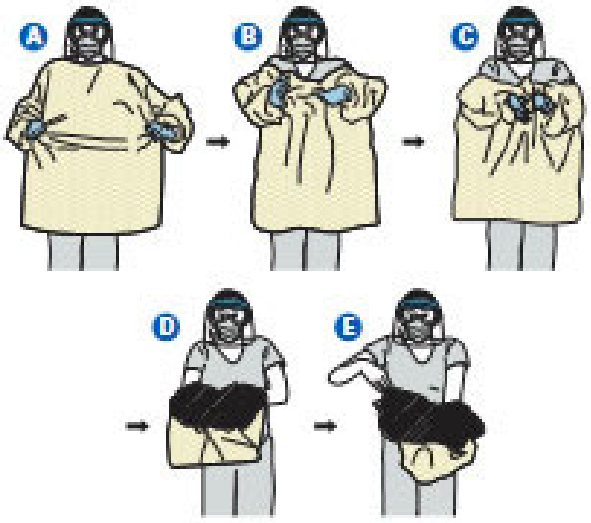
CDC

HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE)
EXAMPLE 2

Here is another way to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. **Remove all PPE before exiting the patient room** except a respirator, if worn. Remove the respirator **after** leaving the patient room and closing the door. Remove PPE in the following sequence:

1. GOWN AND GLOVES

- Gown front and sleeves and the outside of gloves are contaminated!
- If your hands get contaminated during gown or glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp the gown in the front and pull away from your body so that the ties break, touching outside of gown only with gloved hands
- While removing the gown, fold or roll the gown inside out into a bundle
- As you are removing the gown, peel off your gloves at the same time, only touching the inside of the gloves and gown with your bare hands. Place the gown and gloves into a waste container



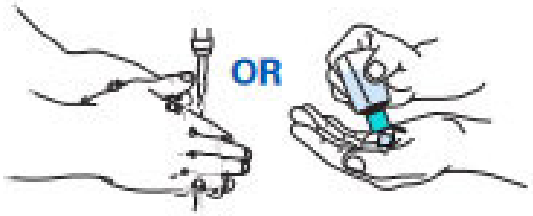
2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band and without touching the front of the goggles or face shield
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a waste container

3. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — DO NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in a waste container

4. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE



PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS BECOME CONTAMINATED AND IMMEDIATELY AFTER REMOVING ALL PPE

CDC

General Reminders:

- PPE must be donned correctly before entering the patient area (e.g., isolation room, unit if cohorting).
- PPE must remain in place and be worn correctly for the duration of work in potentially contaminated areas. PPE should not be adjusted (e.g., retying gown, adjusting respirator/facemask) during patient care.
- PPE must be removed slowly and deliberately in a sequence that prevents self-contamination. A step-by-step process should be developed and used during training and patient care.

Putting on / Taking off PPE

Donning (putting on the gear)

More than one donning method may be acceptable. Training and practice using your healthcare facility's procedure is critical. Below is one example of donning.

- Identify and gather the proper PPE to don. Ensure choice of gown size is correct (based on training).
- Perform hand hygiene using hand sanitizer.
- Put on isolation gown. Tie all of the ties on the gown. Assistance may be needed by another HCP.
- Put on NIOSH-approved N95 filtering facepiece respirator or higher (use a facemask if a respirator is not available).
- If the respirator has a nosepiece, it should be fitted to the nose with both hands, not bent or tented. Do not pinch the nosepiece with one hand.
- Respirator/facemask should be extended under chin. Both your mouth and nose should be protected. Do not wear respirator/facemask under your chin or store in scrubs pocket between patients. *
- » Respirator: Respirator straps should be placed on crown of head (top strap) and base of neck (bottom strap). Perform a user seal check each time you put on the respirator.
- » Facemask: Mask ties should be secured on crown of head (top tie) and base of neck (bottom tie). If mask has loops, hook them appropriately
- around your ears.
- Put on face shield or goggles. Face shields provide full face coverage. Goggles also provide excellent protection for eyes, but fogging is common.
- Perform hand hygiene before putting on gloves. Gloves should cover the cuff (wrist) of gown.
- HCP may now enter patient room.

Doffing (taking off the gear)

More than one doffing method may be acceptable. Training and practice using your healthcare facility's procedure is critical. Below is one example of doffing.

- Remove gloves. Ensure glove removal does not cause additional contamination of hands. Gloves can be removed using more than one technique (e.g., glove-in-glove or bird beak).
- Remove gown. Untie all ties (or unsnap all buttons). Some gown ties can be broken rather than untied. Do so in gentle manner, avoiding a forceful movement. Reach up to the shoulders

and carefully pull gown down and away from the body. Rolling the gown down is an acceptable approach. Dispose in trash receptacle. *

- HCP may now exit patient room.
- Perform hand hygiene.
- Remove face shield or goggles. Carefully remove face shield or goggles by grabbing the strap and pulling upwards and away from head. Do not touch the front of face shield or goggles.
- Remove and discard respirator (or facemask if used instead of respirator).*
- Do not touch the front of the respirator or facemask.
- » Respirator: Remove the bottom strap by touching only the strap and bring it carefully over the head. Grasp the top strap and bring it carefully over the head, and then pull the respirator away from the face without touching the front of the respirator.
- » Facemask: Carefully untie (or unhook from the ears) and pull away from face without touching the front.
- Perform hand hygiene after removing the respirator/facemask and before putting it on again if your workplace is practicing reuse.

OSHA Workers' Rights

All workers have the right to

- A safe workplace.
- Raise a safety or health concern with your employer or OSHA, or report a work- related injury or illness, without being retaliated against.
- Receive information and training on job hazards, including all hazardous substances in your workplace.
- Request a confidential OSHA inspection of your workplace if you believe there are unsafe or unhealthy conditions. You have the right to have a representative contact OSHA on your behalf.
- Participate (or have your representative participate) in an OSHA inspection and speak in private to the inspector.
- File a complaint with OSHA within 30 days (by phone, online or by mail)
- if you have been retaliated against for using your rights.
- See any OSHA citations issued to your employer.
- Request copies of your medical records, tests that measure hazards in the workplace, and the workplace injury and illness log.

Employers must

- Provide employees a workplace free from recognized hazards. It is illegal to retaliate against an employee for using any of their rights under the law, including raising a health and safety concern with you or with OSHA, or reporting a work-related injury or illness.
- Comply with all applicable OSHA standards.
- Notify OSHA within 8 hours of a workplace fatality or within 24 hours of any work-related inpatient hospitalization, amputation, or loss of an eye.
- Provide required training to all workers in a language and vocabulary they can understand.
- Prominently display this poster in the workplace.
- Post OSHA citations at or near the place of the alleged violations.

On-Site Consultation services are available to small and medium-sized employers, without citation or penalty, through OSHA-supported consultation programs in every state.

PLEASE

WASH HANDS

NO FOOD OR DRINK

BIOHAZARD

About the CLIA Program

What is CLIA?

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA)

The objective of the CLIA program is to ensure quality laboratory testing. Any person or facility that performs laboratory tests on human specimens for diagnosis and/or treatment is required by federal law to have a CLIA certificate.

What is a CLIA Waiver Certificate?

Tests approved by the FDA for home or point of service use that require very little training to perform

Requirements for this type of testing are the manufacturer's instructions

Documentation of the manufacture's testing procedure is required

Training of personnel is required along with documentation

A list of approved CLIA-Waived tests can be found at:
http://www.cms.hhs.gov/CLIA/downloads/waivetbl.pdf

In order to perform CLIA-Waived tests, an individual or entity is required to have a CLIA Certificate of Waiver (CLIA-Waiver).

More information: https://www.nmhealth.org/about/dhi/hflc/prop/clia/

CLIA Certificate of Waiver Testing Requirements: Test Administration Processes

Testing sites that perform testing under a CLIA Certificate of Waiver must follow the current manufacturer's test instructions. The following steps should be taken to be sure the current test instructions are being followed:

Keep a copy of the manufacturer's instructions on hand for easy reference.

Check the manufacturer's instructions with each new lot and shipment of test kits to make sure there are no changes from the test kits being used.

File the old manufacturer's instructions and replace with the new copy if there are changes.

Communicate all changes in the manufacturer's instructions to other testing personnel and to the person who directs or supervises testing.

Some manufacturers provide quick reference instructions that can be posted in the testing area. If manufacturer's instructions are updated, the quick reference instructions may need to be updated as well. If your testing site has a procedure manual, the site specific procedure will need to be updated

Preparing for COVID-19 Testing

Testing should be performed in an area with adequate space to safely conduct testing while maintaining patient privacy.

1. Check and record expiration dates of reagents/kits, and discard any reagents or tests that have expired. Check that all kit reagents came from the same kit lot.

2. Perform equipment calibration checks, as needed, following the manufacturer's instructions.

3. Prepare student or staff member prior to testing by providing information from the manufacture's patient information instructions Covid -19 Test and sample collection.

4. Ensure a signed consent form is present that identifies the name of the COVID-19 test, student or staff member's identity by name and date of birth

5. Conduct sample collection test per manufacturer's protocol.

See protocol insert.

Disposal of Hazardous Waste Requirements and Guidance

Per manufacturer's specifications and CDC guidance, waste from COVID-19 test kits should be handled as regulated medical waste. Ready? Set? Test! Patient Testing is Important. Get the right results. (cdc.gov)

All components of the COVID-19 test kit, as well as gloves used by persons administering the test and any grossly contaminated PPE, should be discarded as infectious waste. There are specific labeling and packaging requirements for this type of waste.

Other waste (e.g., trash, such as test packaging and PPE that is not grossly contaminated) generated during administration of the test can be combined with regular trash for disposal.

Infectious waste is to be placed in a rigid container that is leak resistant, impervious to moisture, and strong enough to prevent tearing or bursting from handling. Infectious waste may be placed in a red biohazard bag and then placed in a rigid container to meet the packaging requirements.

The container must be marked with a Biohazard symbol.

NOTE: New Mexico Schools participating in the COVID -19 Testing program must have a school or school district site specific waste management plan as required by the SWR at 20.9.8.13.E(1) NMAC. This plan does not have to be elaborate and should describe how the school or school district trains staff on disposal of hazardous waste, process for handling hazardous waste, and disposal of hazardous waste.

Hiring a New Mexico Licensed Infectious Waste Transporter is strongly recommended to assist with this process and ensure the infectious waste is packaged, transported, disposed of, and tracked appropriately. You should ensure the licensed infectious waste transporter provides containers/packaging to you so that the waste handling will comply with regulatory requirements. Infectious wastes should be kept secure in appropriate containers until pick-up occurs, which should be scheduled at an interval to minimize accumulation of multiple full containers.

Recommended waste disposal plan steps:

1. Contact and contract with a licensed infectious waste transporter for pick-up and disposal of infectious wastes.

2. Get appropriate packaging materials from the contractor for each location that the tests will be administered.

3. Work with the contractor on an appropriate pick-up schedule based on the number of tests the site anticipates using, the size of containers provided, number of testing locations, and any other facility-specific factors.

Additional Resources

"Good Laboratory Practices for Waived Testing Sites" Morbidity and Mortality Weekly Report (MMWR), Recommendations and Reports; November 11, 2005, vol 54(RR13);1-25. http://www.cdc. gov/mmwr/preview/mmwrhtml/rr5413a1.htm

"READY? SET? TEST!" poster http://wwwn.cdc.gov/clia/Resources/WaivedTests/default.aspx

"Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Tests Waived Under the Clinical Laboratory Improvement Amendments of 1988." http://www.cdc.gov/hiv/pdf/testing_qa_guidlines.pdf

CLIA: http://www.cms.gov/Regulations-and-Guidance/Legislation/ CLIA/index.html?redirect=/CLIA/

CLIA CW Application: http://www.cms.gov/Medicare/CMS-Forms/ CMS-Forms/downloads/cms116.pdf

CLIA – State Agency Contacts: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/State_Agency_and_Regional_Office_ CLIA_Contacts.html

FDA's CLIA Waived Test List: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/ analyteswaived.cfm

Health Insurance Portability and Accountability Act (HIPAA): http://www.hhs.gov/ocr/privacy/

CDC: http://wwwn.cdc.gov/clia/Resources/WaivedTests/

The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) Biosafety link: http://www.cdc.gov/biosafety/

OSHA publications and links: http://www.osha.gov/pls/publications/publication.html