SARS-CoV-2 / COVID-19
Laboratory-Related Terminology & Training
Intended Use & Disclaimer

• This resource is intended to be used and shared with those involved in the COVID-19 response to help foster a shared understanding of laboratory-related terms.

• Names of individual manufacturers or products are only used for educational purposes and do not specifically denote endorsement by the Oregon Health Authority (OHA) or the Oregon State Public Health Laboratory (OSPHL).

• This content may be used to supplement COVID-19 training programs.
Coronavirus

• A family of viruses that cause illness ranging from the common cold to more severe diseases, such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV).

• A novel coronavirus is a new coronavirus that has not been previously identified.
SARS

• Severe acute respiratory syndrome (SARS) is a viral respiratory illness caused by a coronavirus called SARS-associated coronavirus (SARS-CoV).

• SARS was first reported in Asia in February 2003. The illness spread to more than two dozen countries in North America, South America, Europe, and Asia before the SARS global outbreak of 2003 was contained.

• Since 2004, there have not been any known cases of SARS reported anywhere in the world.
SARS CoV-2

- Severe Acute Respiratory Syndrome (SARS) CoV-2 is the name of the novel coronavirus that causes the disease COVID-19.
COVID-19

• The name of the disease caused by the novel coronavirus, SARS-CoV-2, and is short for “Coronavirus Disease 2019.”

• COVID-19, is not the same as the coronaviruses that commonly circulate among humans and cause mild illness, like the common cold. A diagnosis with more common coronavirus types 229E, NL63, OC43, or HKU1 is not the same as a COVID-19 diagnosis.
Specimens & Samples

• Terms are often used interchangeably, but they are different
  – **SAMPLE**: A selected subset of a population. A portion or part of a population or whatever is being studied. A sample may be random or non-random and it may be representative or non-representative.
  – **SPECIMEN**: A portion of blood, urine, or other body fluid or tissue taken for scientific and laboratory testing.
    • *Material collected from a patient that will be used for laboratory testing*
Specimens for Testing

- All testing for SARS-CoV-2 / COVID-19 should be conducted in consultation with a healthcare provider.
- Specimens should be collected as soon as possible once a decision has been made to pursue testing, regardless of the time of symptom onset.
- For initial diagnostic testing for SARS-CoV-2, CDC recommends collecting and testing an upper respiratory specimen.
Respiratory Specimens

• Upper respiratory tract specimens
  – Nasopharyngeal (NP) swab
  – Oropharyngeal (OP, throat) swab
  – Nasal mid-turbinate (NMT) swab
    • Also called “deep nasal” swab
  – Anterior nares (nasal) swab
  – Nasopharyngeal wash/aspirate or nasal wash/aspirate

• Lower respiratory tract specimens
  – Bronchoalveolar lavage, tracheal aspirate, pleural fluid, lung biopsy
  – Sputum

NOTE: Not all testing labs accept all specimen types!
You need to confirm acceptable specimens with each testing lab.
Acceptable Specimens

- Always consult with the testing lab specific requirements for acceptable specimens to submit for laboratory testing.
- Will depend on several factors:
  - Which laboratory you are sending specimens to for testing
  - Which SARS-CoV-2 / COVID-19 specific test is being performed
  - What specimen types the lab validated for testing
  - What the testing laboratory specific requirements are (e.g., temperature)
- Testing laboratories will provide acceptable specimen criteria and will have a rejection policy for unsatisfactory specimens
- OSPHL Test Menu Page:
  - [https://www.oregon.gov/oha/PH/LaboratoryServices/CommunicableDiseaseTesting/Pages/index.aspx](https://www.oregon.gov/oha/PH/LaboratoryServices/CommunicableDiseaseTesting/Pages/index.aspx)
Specimen Integrity

• Proper collection of specimens is the most important step in the laboratory diagnosis of infectious diseases.

• A specimen that is not collected correctly may lead to false negative test results, or may be rejected as “unsatisfactory” by the testing laboratory.
Collecting Specimens

• Instructions for collecting specific types of specimens are provided by the CDC, public health departments and often by the testing laboratories.

**Nasopharyngeal Specimen Collection**
COVID-19 Testing with SARS-CoV-2-RNA, Qualitative Real-Time RT-PCR

The test has not been FDA cleared or approved or authorized. The test has been validated according to CLIA, but the FDA’s independent review of this validation is pending.

1. Open the individual collection package that contains the swab and Viral Transport Medium tube. Set the tube aside before beginning to collect the specimen.

2. Open the collection swab wrapper by peeling open the top of the wrapper. Remove the swab, taking care not to touch the tip of the swab or lay it down.

3. Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft across the scoreline.

4. Gently insert the swab into the nostril. Keep the swab near the septum floor of the nose while gently pushing the swab into the post nasopharynx.

5. As a visual reference, the swab should be inserted about half the distance from the opening of the patient’s nostril and the ear. Rotate the swab several times.

6. While holding the swab in the same hand, aseptically remove the cap from the tube. Insert the swab into the tube with the transport medium.

7. Identifying the scoreline, break the swab shaft against the side of the tube. If needed, gently rotate the swab shaft to complete the breakage. Discard the top portion of the swab shaft. Avoid splashing contents on the skin. Wash with soap and water if exposed.

8. Replace the cap onto the tube and close tightly. Samples should be shipped frozen (preferred). However, samples can be shipped refrigerated at 2°C–8°C, and are stable at this temperature for 72 hours. Cold pack/pouches must be used if placing specimens in a cooler box for courier pick-up. Specimens should be shipped overnight to your local Quest Diagnostics accessioning laboratory according to standard operating procedures. SARS-CoV-2 DNA Qualitative Real-Time RT-PCR test is not a STAT test and STAT pick-up cannot be ordered.

*Example from Quest Diagnostic Laboratories*
Specimen Collection Events

• Planned events coordinated with local and state public health.
• Used to collect specimens from large or targeted populations.
• Collected specimens will be transported to a lab for testing.
  - “Testing” usually does not occur at “collection events”
Specimen Collection Kits

• Items needed to collect a specimen for lab testing
  – (1) Swab
  – (1) Tube / vial of transport media
  – (1) Specimen transport bag
  – (1) Lab test request form / lab requisition form

Don’t forget- you will also need PPE (not pictured) to collect and handle specimens!
Swabs / Applicators

- Used to collect proper specimens such as nasopharyngeal (NP) or oropharyngeal (OP) swabs
- Various types are allowable for use for COVID lab testing
  - E.g., Flocked swabs, FLQ swabs, synthetic fibers, etc.
- Some types **not** allowable (e.g., calcium alginate, wood shafts)
Transport Media

- Used to maintain specimen integrity after collection and for storage and transport to the lab for testing
- **For COVID testing, transport media may be:**
  - Viral transport media (VTM)
  - Universal transport media (UTM)
  - Amies transport media
  - Sterile saline / normal
- **Will be dependent on available supplies and which lab is conducting which COVID-19 test**
Specimen Transport Bags

- Used as a leakproof secondary container to transport specimens to the lab for testing
  - Must contain absorbent material
  - Must display a biohazard symbol
  - Test request form must go outside the bag in the outer pouch

*Often incorrectly referred to as a ‘biohazard bag’*
Biohazard Bags

• Term typically used to describe infectious “red bag” regulated medical laboratory waste

*Term is often incorrectly used to refer to ‘specimen transport bags’*
Lab Test Request Form aka Lab Requisition Form

• Form that must be completed and submitted along with each specimen to the testing lab and contains:
  – Secure patient info
  – Lab test being requested / ordered
  – Specimen information such as:
    • Date of collection
    • Specimen type (e.g., NP swab, etc.)

• OSPHL test request forms:  
  www.bitly.com/phl-forms
Specimen Notes

- Always consult with the testing lab specific requirements for acceptable specimens to submit for lab testing.

- There are some special requirements with some specimens:
  - E.g., Use of synthetic fiber swabs with plastic or wire shafts
  - E.g., Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing
  - E.g., Collecting only one, or more than one specimen type such as only NP, or NP plus OP, and possibly combining NP and OP in a single tube to maximize test sensitivity and limit the use of testing resources
  - E.g., Use of flocked or spun polyester swabs
  - E.g., Sample both nostrils with same swab
  - E.g., Required amount/volume of specimen needed for testing
  - E.g., What has been validated and authorized for testing
Specimen Handling

- Specimen (swabs) should be placed immediately into a sterile transport tube / vial containing 2-3 mL of acceptable transport media, such as:
  - Viral transport medium (VTM)
  - Liquid Amies transport medium
  - Universal transport medium (UTM)
  - Sterile normal saline solution
  - Phosphate buffered saline (PBS)

- Unless using a test designed to analyze a specimen directly, such as some point of care tests.
Specimen Labeling

• Label each specimen tube / vial with all of the required information, such as:
  – Patient’s name, identification number, specimen type, date collected, etc.

NOTE: At least two unique identifiers will be required to link the specimen with its test request form!
Temperature Ranges

• Room temp / ambient (15-30°C or 59-86°F)
  – Usually between (20-25°C or 68-77°F)

• Refrigerated (2-8°C or 35-46°F)
  – Average usually 5°C or 40°F

• Frozen (≤ 0°C or ≤ 32°F)
  – Usually between -58° to 5°F (or -50° to -15°C)

• If lab specimens need to be stored frozen, they require ultra-low freezers capable of reaching ≤ -70°C or ≤ -94°F, and will require dry ice for shipping
Storage Conditions

• Need to know storage condition requirements for:
  – Transport media stored without specimens
  – Transport media with specimens prior to shipping
  – Specimens inside shipping containers
  – Other lab related supplies and materials like test kits

• Avoid specimen freeze-thaw cycles when possible as it may effect specimen integrity and lab test results.
Specimen Temperature

• Store collected specimens at the same temperature they will need to be at for shipping/transport to testing lab.
  – Always consult with the testing lab for specimen shipping temperature requirements
  – Specimen shipping temperature will depend on when the samples will be tested

• Store specimens refrigerated (2-8°C) for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70°C or below.
Transport / Shipping

• Pack and ship suspected and confirmed SARS-CoV-2 patient specimens, cultures, or isolates as UN 3373 Biological Substance, **Category B**
  – Personnel must be trained to pack and ship according to the DOT and IATA regulations and in a manner that corresponds to their function-specific responsibilities.
Category B Shipping

• U.S. Department of Transportation (DOT) Category B “General Awareness” shipping training requirements:
  – 49 CFR 172.700 & 49 CFR 173.199

• Category B shipments need:
  – Rigid outer container
  – Hazard labels
  – Triple packaging
  – Absorbent material
  – “To” and “From” listed
Couriers and Carriers

• Some testing labs provide their own courier services
• Several commercial carrier options (UPS, USPS, FedEx, etc.)

• OSPHL contracted courier services (Senvoy):
• [www.bitly.com/phl-courier](http://www.bitly.com/phl-courier)
Testing Guidelines

- **Outline testing requirements and recommendations.**
- **CDC Testing Guidelines**
- **OHA Testing Guidelines**
  - [www.healthoregon.org/coronavirushcp](http://www.healthoregon.org/coronavirushcp)
Laboratory Testing

• Clinical laboratories performing diagnostic and serological COVID-19 testing must be CLIA certified.

• **Diagnostic Testing:** Provides laboratory results to help make informed decisions about patient care.

• **Serology / Antibody Testing:** Looks for the presence of antibodies, which are specific proteins made in response to infections. Antibodies are detected in the blood of people who are tested after infection; they show an immune response to the infection. Antibody test results are especially important for detecting previous infections in people who had few or no symptoms.
CLIA

- **Clinical Laboratory Improvement Amendments of 1988**
  - Federal Program that establishes quality laboratory standards to protect patient safety and improve healthcare.

- **CLIA Law & Regulations (42 CFR 493)**
  - Lab Requirements for Standards and Certification
CLIA System

- Three federal agencies are responsible for CLIA and assuring quality laboratory testing:
  - Food and Drug Administration (FDA)
  - Center for Medicaid Services (CMS)
  - Centers for Disease Control (CDC)

**FDA**
Determines Test Complexity Categorization

**CMS**
Clinical Lab Oversight
- Issues certificates
- Monitors Proficiencies
- Conducts inspections

**CDC**
Technical Consultation
CLIA Certified Testing

• Any facility examining human specimens for diagnosis, prevention, treatment of a disease or for assessment of health must register with CMS and obtain CLIA certification that corresponds to the complexity of tests performed.

• CLIA regulations apply to all facilities in the U.S. that perform laboratory testing on human specimens to assess health, diagnosis disease, or measure results of methods used to prevent or treat disease.
  – Clinical labs, physician offices, skilled nursing facilities, pharmacies, etc.
Testing Complexity Types

Test Complexity Categories:

1. Waived Testing

Non-Waived Testing

2. Moderate Complexity Testing (42 CFR 493.1405)

3. High Complexity Testing (42 CFR 493.1483)
CLIA Certified Laboratories

• The more complicated the test, the more stringent the specific CLIA quality standards and requirements are for personnel qualifications and responsibilities.
  
  Waived → Moderate Complexity → High Complexity

• Labs must be certified at the highest level of testing performed.

US Clinical Laboratory Community

260,000 Laboratories in USA

13.8 Billion tests per year

That's over 42 tests per year for every person living in the United States

800,000 Lab Personnel

https://www.cdc.gov/CSELS/dls/
Testing Data in the U.S.

Updated June 18, 2020

<table>
<thead>
<tr>
<th>TOTAL TESTS REPORTED</th>
<th>POSITIVE TESTS REPORTED</th>
<th>% OF POSITIVE TESTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>26,500,497</td>
<td>2,691,985</td>
<td>10%</td>
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</table>

OHA Testing Overview


PUBLIC HEALTH DIVISION
OREGON STATE PUBLIC HEALTH LABORATORY
OHA Testing Information

COVID-19 Testing Basics

Who should be tested?

Many people are interested in testing for COVID-19 out of concern for themselves and their loved ones. If you have trouble breathing or feel very ill, contact your healthcare provider or, in case of emergency, call 911.

Healthcare providers may decide to have you first tested for other illnesses, like the flu, based on your possible exposure history and any other symptoms you might have.

- Individuals who feel very ill should seek appropriate care. If it is an emergency, call 911. If it is not an emergency but you feel sick enough to need
SARS-CoV-2 / COVID-19 Lab Tests

- FDA Emergency Use Authorization (EUA) website lists currently authorized medical devices, PPE, and in vitro diagnostics

- All COVID-19 / SARS-CoV-2 laboratory tests currently are under EUA and testing labs must comply with the EUA requirements and the manufacturer package inserts.
Package Insert

• Instructions provided by a manufacturer that describe how to use their product as intended by the manufacturer.

• It is critical that all testing labs closely follow the instructions provided within a package insert.

• All SARS-CoV-2 / COVID-19 testing must follow all package insert instructions and EUA requirements.
EUA

- During a public health emergency, the FDA can use its Emergency Use Authorization (EUA) authority to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives.
  - E.g., Ebola, Zika, Enterovirus D68, COVID-19
CLIA Waived Testing

• Currently, several tests have been authorized by FDA under the EUA for COVID-19 / SARS-CoV-2 laboratory testing.
• Sites that perform only waived testing must have a CLIA Certificate of Waiver.
• Waived tests are defined by CLIA as “simple tests with a low risk for an incorrect result”.
• Some COVID-19 molecular waived test examples:
  – Abbott Diagnostics, ID NOW COVID-19
  – Cue Health COVID-19
  – Accula SARS-CoV-2
  – Cepheid Xpert Xpress SARS CoV-2
  – Quiedel SOFIA SARS Antigen FIA

“Point of care” testing is CLIA waived testing.
CLIA Waived Test Examples

Abbott ID NOW  
https://www.abbott.com/IDNOW.html

CUE Health COVID-19 Test  
https://www.cuehealth.com/covid-19

Cepheid GeneXpert  
https://www.cepheid.com/coronavirus

Accula SARS CoV-2  
https://www.mesabiotech.com/coronavirus
Moderate and High Complexity Testing

- All non-waived tests are classified as either moderate or high complexity.

- In general, the more complicated the test, the more stringent the requirements under CLIA.
  - Non-waived testing is subject to inspection, and must meet the CLIA quality system standards, such as those for proficiency testing, quality control and assessment, and personnel requirements.
  - The standards for moderate and high complexity testing differ only in the personnel requirements.
  - CLIA certification is based on the categorization of test(s) being performed.
Moderate and High Complexity Testing for COVID-19

- **LOTS** of tests are currently authorized for COVID-19 by FDA!!

Laboratory Equipment & Materials

- Several equipment, instruments and materials are needed for conducting laboratory testing, such as:
  - Extraction equipment
  - Safety equipment
    - Biological safety cabinets (BSCs), PPE, splash guard barriers, etc.
  - Testing platforms
    - Molecular, serological, etc.
  - Testing instruments
    - PCR machines (thermocyclers), pipettes, thermometers, etc.
  - Reagents (e.g., test kits)
Laboratory Extraction Equipment

• Reagents, instruments and other materials needed to process specimens, and extract nucleic acids (DNA or RNA) or other target material from organisms / pathogens of interest
Laboratory Testing Equipment

- Instruments needed for conducting laboratory tests, such as:

  - ABI 7500 Fast Dx
  - Abbott ID NOW
  - Hologic Panther
Test Kits & Control Kits

• Items needed to conduct certain laboratory tests on certain testing platforms or instruments
  – Reagents, positive & negative controls, reaction tubes, etc.

Specimen collection kits are often incorrectly referred to as “Test kits”
Laboratory Surge Testing Capacity

• Laboratory testing capacity can be defined in 3 categories:
  – Standing capacity
  – Internal surge capacity
  – Overall surge capacity

• And several factors can affect surge capacities:
  – Infrastructure
  – Staffing
  – Operations

Image provided courtesy of APHL
Standing Capacity

• Total volume of testing a lab can perform or absorb with no or minimal operational changes, within normal hours of operation, using existing staff and without curtailing other routine laboratory activities.

• It includes routine modifications to daily work assignments and/or staffing changes due to reagent shortages, equipment failures and personnel shortages (e.g., absences due to illness or vacation).

• It also includes routine absorbable capacity, which is the additional volume of testing that a laboratory can perform with minimal operational changes, such as during a small-scale natural disease outbreak, small-scale suspicious event or short-term planned events, such as a major political conference or sporting event.

Internal Surge Capacity

- The sudden and sustained increase in the volume of testing that a lab can perform in an emergency situation, implementing substantial operational changes as defined in laboratory emergency response plans and using all resources available within the laboratory.
- It may require movement of staff to support surge activities, including reassigning technical staff, assigning support staff to cover administrative tasks and the addition of extra shifts.

Overall Surge Capacity

- The sudden and sustained increase in the volume of testing that a lab can perform in an emergency situation, implementing substantial operational changes as defined in laboratory emergency response plans and using all resources available, including resources internal and external to the state public health or military or environmental laboratory system such as personnel, equipment or facilities.

- It may require the actual transfer of personnel, equipment and/or specimens from or to a local facility that has been previously determined to meet technical requirements and for which appropriate Memoranda of Understanding/Agreement have already been established.

- Overall surge would also include “inter-state” surge agreements, especially with bordering states.

Factors Affecting Surge Capacity

**Infrastructure Factors:**
- BSL-2 and BSL-3 facilities and total laboratory bench space
- Biological safety cabinets and chemical fume hoods
- Reagent supply (amount, type, expiration date) and access to additional/different reagents
- Analytical equipment (PCR, MALDI-TOF, GC/MS, LC/MS, ICP/MS, etc.)
- Space for intake, processing and storage of samples
- Versatility/capacity of instruments/equipment (single vs. multiple use; tests per hour/shift)
- Standardized instrumentation in multiple lab areas (allows for reallocation of testing)
- Robotic technologies to enhance throughput processing
- Electrical capacity/emergency power supply
- Personal protective equipment
- Biosafety and biosecurity (containment)
- Disposable lab supplies
- Autoclave/incinerator (for “terminal decontamination”)
- Ventilation capacity
Factors Affecting Surge Capacity

- **Staffing Factors:**
  - Adequately trained, cross-trained and competent staff to perform assays
  - Auxiliary/surge staff
  - Staff vaccinations and agent-specific prophylaxis
  - Staff with appropriate clearances/licensure
  - Support staff (answer phones, data entry, etc.)
  - Support for staff during an incident (e.g., psychological/behavioral support; food, comfort and rest during prolonged shifts; family care; transportation to and from work)
  - Information Technology (IT) staff to assist with IT issues during or after an incident
  - Capability of staff to implement new technologies for new threats
  - Stability of staffing (absenteeism due to incident, illness, family emergencies, rate of turnover)
  - Capability to hire rapidly
  - Staff sharing agreements (staff from outside lab, familiarity with laboratory and policies)
Factors Affecting Surge Capacity

- **Operational Factors:**
  - Type of samples
  - Screening, triage and processing of routine and emergency samples
  - Ability to reassign staff to new tasks
  - Quality assurance and quality control
  - Test sharing ability with other laboratories
Laboratory Test Results

• Testing laboratories have result reporting requirements
  – Results provided back to the clinician ordering the lab test
  – Notifiable diseases and conditions reported to public health

• CDC COVID-19 Laboratory Data Reporting
Interpreting Laboratory Results

The U.S. Dept of Health and Human Services (HHS) has created a guidance document to assist with the interpretations of lab testing results.

OHA Disease Reporting

- Notifiable diseases and conditions that must be reported to public health from laboratories and clinicians [www.healthoregon.org/diseaseReporting](http://www.healthoregon.org/diseaseReporting)
ELR (Electronic Lab Reporting)

- ELR generally refers to the automated messaging of laboratory reports sent using one or more electronic communication protocols.
- ELR improves the reporting of notifiable conditions, which in turn benefits public health surveillance and preparedness efforts.
- CDC ELR Information:
  - [https://www.cdc.gov/elr/about.html](https://www.cdc.gov/elr/about.html)
  - [https://www.cdc.gov/ehrmeaningfuluse/elr.html](https://www.cdc.gov/ehrmeaningfuluse/elr.html)
- OHA ELR Information
  - [www.healthoregon.org/elr](http://www.healthoregon.org/elr)
Biosafety

Protects people from dangerous pathogens

• Combination of appropriate work practices, safety equipment (including personal protective equipment (PPE)), and facility design employed to contain potentially infectious microorganisms and hazardous biological materials (e.g., toxins), to reduce the exposure risk to workers, the environment and the public and to prevent laboratory acquired infections (LAIs).
Biosafety in the Laboratory

• Follow **Standard Precautions** when handling clinical specimens, all of which may contain potentially infectious materials.
  – Including hand hygiene and the use of PPE, such as laboratory coats or gowns, gloves, and eye protection.

• Follow routine laboratory practices and procedures for decontamination of work surfaces and management of laboratory waste.

• CDC Standard Precaution Info:
Laboratory Infectious Waste

• Laboratories regularly produce infectious waste and other hazardous waste such as chemical waste.
  – Hazardous waste is regulated nationally and locally.

• Handle laboratory waste from testing suspected or confirmed COVID-19 patient specimens as all other biohazardous waste in the laboratory.

• Currently, there is no evidence to suggest that this laboratory waste needs any additional packaging or disinfection procedures.
Biosafety Training

• Provide biosafety awareness training & resources to staff
  – PPE donning & doffing
  – Disinfection capabilities & practices
  – Biosafety levels and organism risk groups
  – Biosafety cabinet operations
  – Specimen handling
  – Waste handling and disposal
Administrative Controls

- Administrative controls are those that modify workers’ work schedules and tasks in ways that minimize their exposure to workplace hazards.

- Examples include:
  - Developing relevant lab specific plans, policies and trainings such as chemical hygiene plan, bloodborne pathogens exposure control plan, etc.
  - Conducting biological risk assessments

- Administrative controls and PPE are frequently used with existing processes where hazards are not particularly well controlled.
Engineering Controls

• Protect workers by removing hazardous conditions or by placing a barrier between the worker and the hazard. Design and install engineering controls to reduce or eliminate exposures by shielding healthcare personnel from infected individuals or specimens.

• Examples of engineering controls include:
  – Physical barriers or partitions (e.g., splash guard)
  – Air-handling systems (with appropriate directionality, filtration, exchange rate, etc.) that are properly installed and maintained
  – Biological safety cabinets
  – Sealed centrifuge cups
Biological Safety Cabinet (BSC)

• Commonly called a “hood”
• Primary piece of safety equipment in clinical laboratories
• Provides protection to the user, the testing environment, and keeps the product / samples clean
  – Traps particulates only. Ineffective against fumes and vapors.
Biological Risk Assessment

• All laboratories should routinely perform a site-specific and activity-specific risk assessment to identify and mitigate risks.

• Risk assessments and mitigation measures are dependent on:
  – The procedures performed
  – Identification of the hazards involved in the process and/or procedures
  – The competency level of the personnel who perform the procedures
  – The laboratory equipment and facility
  – The resources available
Personal Protective Equipment (PPE)

- Specialized clothing or equipment worn by an employee for protection against a hazard.
  - General work clothes (e.g., uniforms, pants, shirts) not intended to function as protection against a hazard are not considered to be PPE.

Preferred PPE – Use N95 or Higher Respirator

- Face shield or goggles
- N95 or higher respirator
- Face shield or goggles
- One pair of clean, non-sterile gloves
- Isolation gown

Acceptable Alternative PPE – Use Facemask

- Face mask
- N95 or higher respirators are preferred but facemasks are an acceptable alternative.
- Face shield or goggles
- One pair of clean, non-sterile gloves
- Isolation gown
Strategies to Optimize the Supply of PPE and Equipment

Personal protective equipment (PPE) is used every day by healthcare personnel (HCP) to protect themselves, patients, and others when providing care. PPE helps protect HCP from potentially infectious patients and materials, toxic medications, and other potentially dangerous substances used in healthcare delivery.

PPE shortages are currently posing a tremendous challenge to the U.S. healthcare system because of the COVID-19 pandemic. Healthcare facilities are having difficulty accessing the needed PPE and are having to identify alternate ways to provide patient care.

Respiratory Protection

- **Respirators:** A personal protective device that is worn on the face or head and covers at least the nose and mouth.

- A respirator is used to reduce the wearer’s risk of inhaling hazardous airborne particles (including infectious agents), gases or vapors.

- Respirators, including those intended for use in healthcare settings, are certified by the CDC/NIOSH.

- **Face masks and face coverings:**
  - Not certified by CDC/NIOSH
  - Offer some protection, but less than a CDC/NIOSH certified respirator
  - Currently

https://www.cdc.gov/niosh/npptl/hospresptoolkit/training.html
# Masks vs. Respirators

## Understanding the Difference

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<thead>
<tr>
<th></th>
<th>Surgical Mask</th>
<th>N95 Respirator</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Testing and Approval</strong></td>
<td>Cleared by the U.S. Food and Drug Administration (FDA)</td>
<td>Evaluated, tested, and approved by NIOSH as per the requirements in 42 CFR Part 84</td>
</tr>
<tr>
<td><strong>Intended Use and Purpose</strong></td>
<td>Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer’s respiratory emissions.</td>
<td>Reduces wearer’s exposure to particles including small particle aerosols and large droplets (only non-oil aerosols).</td>
</tr>
<tr>
<td><strong>Face Seal Fit</strong></td>
<td>Loose-fitting</td>
<td>Tight-fitting</td>
</tr>
<tr>
<td><strong>Fit Testing Requirement</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>User Seal Check Requirement</strong></td>
<td>No</td>
<td>Yes, Required each time the respirator is donned (put on)</td>
</tr>
<tr>
<td><strong>Filtration</strong></td>
<td>Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection</td>
<td>Filters out at least 95% of airborne particles including large and small particles</td>
</tr>
<tr>
<td><strong>Leakage</strong></td>
<td>Leakage occurs around the edge of the mask when user inhales</td>
<td>When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales</td>
</tr>
<tr>
<td><strong>Use Limitations</strong></td>
<td>Disposable, Discard after each patient encounter.</td>
<td>Ideally should be discarded after each patient encounter and after aerosol-generating procedures. It should also be discarded when it becomes damaged or deformed; no longer forms an effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult; or if it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.</td>
</tr>
</tbody>
</table>

The CDC & NIOSH have developed several respiratory guidance materials:

- [https://www.cdc.gov/niosh/npptl/respirators/testing/default.html](https://www.cdc.gov/niosh/npptl/respirators/testing/default.html)
Droplets

- **Droplets** traditionally are defined as larger infectious particles (>5 μm in diameter) that rapidly fall out of the air, contaminating gloves, the immediate work area, and the mucous membranes of the persons performing the procedure.

  - Examples of infectious agents that are transmitted via the droplet route include *Bordetella pertussis*, influenza viruses, adenovirus, *Mycoplasma pneumoniae*, SARS-associated coronavirus (SARS-CoV), group A *Streptococcus*, and *Neisseria meningitidis*. 
Droplet Nuclei & Droplet Spread

**Droplet Nuclei:** The residue of dried droplets that may remain suspended in the air for long periods, may be blown over great distances, and are easily inhaled into the lungs and exhaled.

**Droplet Spread:** The direct transmission of an infectious agent from a reservoir to a susceptible host by spray with relatively large, short-ranged aerosols produced by sneezing, coughing, or talking.
Infectious Aerosols

- **Infectious aerosols** are small liquid or solid particles suspended in the air that contain infectious agents.
- They can disperse throughout the laboratory and remain infective over time and distance.
- These particles are of a size that may be inhaled into the lower respiratory tract (<5 μm in diameter).
  - Examples of organisms transmitted by aerosols include spores of *Aspergillus* spp., *Mycobacterium tuberculosis*, rubeola virus (measles), and varicella-zoster virus (chickenpox).
Contaminated

• State of having actual or potential contact with microorganisms.

• As used in health care, the term generally refers to the presence of microorganisms that could produce disease or infection.
Disinfection

- *Disinfection* describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects. In health-care settings, objects usually are disinfected by liquid chemicals or wet pasteurization. Each of the various factors that affect the efficacy of disinfection can nullify or limit the efficacy of the process.
  - Thermal or chemical destruction of pathogenic and other types of microorganisms.
  - Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).
Disinfectant

- Disinfectants are usually a chemical agent (but sometimes a physical agent) that destroys disease-causing pathogens or other harmful microorganisms but might not kill bacterial spores. It refers to substances applied to inanimate objects.

- EPA groups disinfectants by product label claims of “limited,” “general,” or “hospital” disinfection.

- Approved disinfectants for SARS-CoV-2 can be found on the EPA List “N”

https://cfpub.epa.gov/giwiz/disinfectants/index.cfm
Decontamination

• According to OSHA, “the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal” [29 CFR 1910.1030]. In health-care facilities, the term generally refers to all pathogenic organisms.

• Decontamination removes pathogenic microorganisms from objects so they are safe to handle, use, or discard.

• Decontaminate work surfaces and equipment with appropriate disinfectants by using an EPA-approved disinfectant.

• Follow the manufacturer’s recommendations for use, such as dilution, contact time, and safe handling.
Disinfection Contact Time

• Instructions for disinfecting a laboratory work area are to be included in each lab standard operating procedure (SOP) and must include what PPE to wear, how to clean surfaces, what disinfectant to use, and how to dispose of cleaning materials.

• **Contact time** is a critical and necessary part of the instructions and should be available near the lab area for easy reference.

• “**Contact time**” is the amount of time needed for a disinfectant to be applied in order for it to work appropriately (letting the disinfectant sit on the contaminated surface long enough to kill the target microorganisms).
  
  – **Always follow the disinfectant manufacturer instructions for use.**

https://www.cdc.gov/mmwr/pdf/other/su6101.pdf
Sterilization

- **Sterilization** describes a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods. Steam under pressure, dry heat, EtO gas, hydrogen peroxide gas plasma, and liquid chemicals are the principal sterilizing agents used in health-care facilities.
  - E.g., Autoclave
Autoclave

- Device that sterilizes instruments or other objects using steam under pressure. The length of time required for sterilization depends on temperature, vacuum, and pressure.
Cleaning

• **Cleaning** is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products.

• Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of the processes.
Antiseptic

• Substance that prevents or arrests the growth or action of microorganisms by inhibiting their activity or by destroying them.

• The term is used especially for preparations applied topically to living tissue.
FDA Testing Supply Guidance

- The FDA provides a great resource that describes testing procedures, processes and materials
Want to Know More About Lab Specimens and Lab Testing?

• Check out these free CDC trainings:
  – “Life of a Specimen”
    • https://www.cdc.gov/labtraining/training-courses/lab-infomatics/life-of-a-specimen.html
  – “Life of a Result”
    • https://www.cdc.gov/labtraining/training-courses/lab-infomatics/life-of-a-result.html
Image References

Unless specifically noted within this presentation, all images used were obtained from the CDC Public Health Image Library, from other federal publications or sources which are free of copyright restrictions, or were provided/obtained by the Oregon State Public Health Laboratory.
CDC Resources and References

- CDC COVID-19 Homepage

- CDC Information for Laboratories about COVID-19

- CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19

- CDC Interim Guidelines for Biosafety and COVID-19

- CDC COVID-19 Testing Overview
Biosafety Resources and References

- CDC Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories

- WHO Laboratory Biosafety Guidance Related to the Novel Coronavirus (2019 nCoV)

- CDC Interim Guidelines for Biosafety and COVID-19

- APHL Risk Assessment Best Practices

- EPA List “N” of Disinfectants:
  - https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2
Testing Resources and References

- FDA FAQs on SARS-CoV-2 Testing
- FDA Emergency Use Authorizations (EUAs)
- CDC COVID-19 Testing Info
- CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19
- OHA Testing Guidelines
  - www.healthoregon.org/coronavirushcp
CLIA Resources & References

CLIA Law & Regulations
• https://www.cdc.gov/clia/law-regulations.html

CLIA Waived Testing
• https://www.cdc.gov/clia/waived-tests.html
• http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm
• http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm

CLIA Certification

CLIA Categorization
• https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clia-categorizations

CLIA Test Complexities
• https://www.cdc.gov/clia/test-complexities.html
For Additional Questions, Please Contact

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Thank you

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