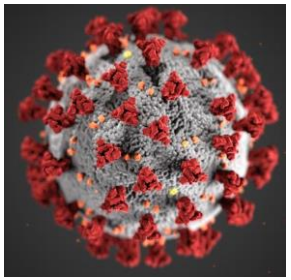
SARS-CoV-2 / COVID-19 Laboratory-Related Terminology & Training



Oregon Health Authority

PUBLIC HEALTH DIVISION
OREGON STATE PUBLIC HEALTH LABORATORY

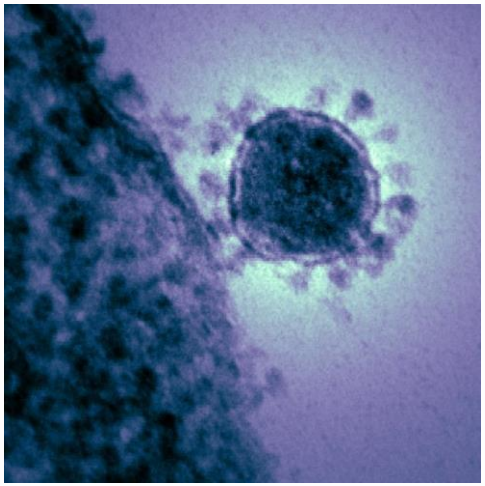
Intended Use & Disclaimer

- 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.



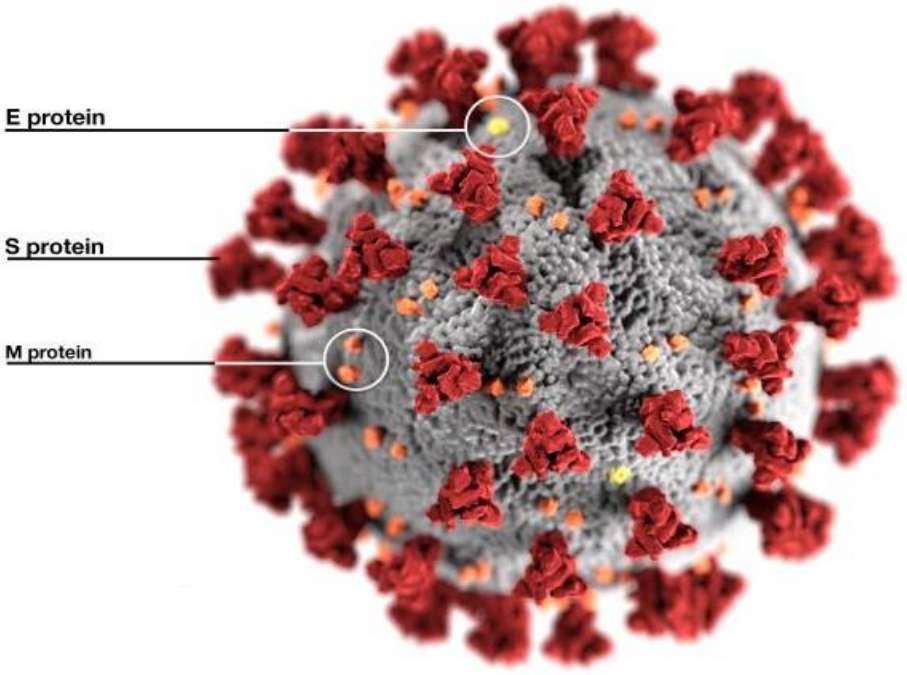
MERS-CoV

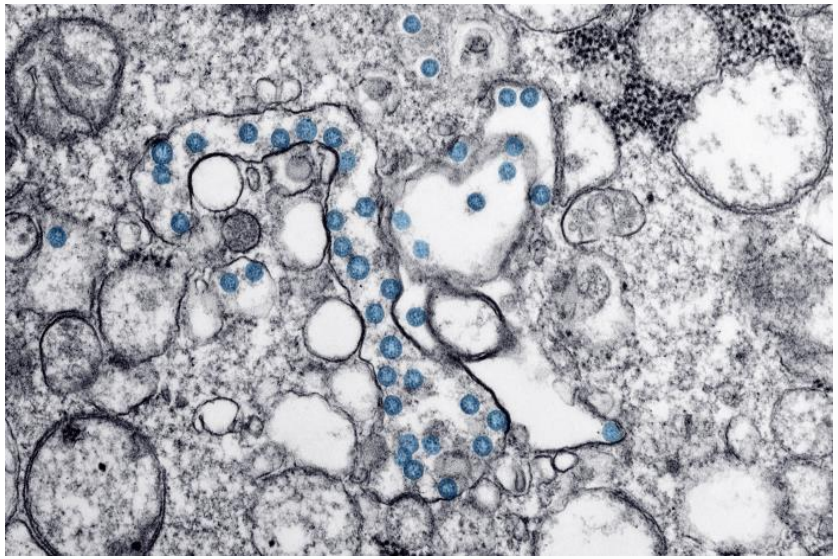
SARS

- 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.



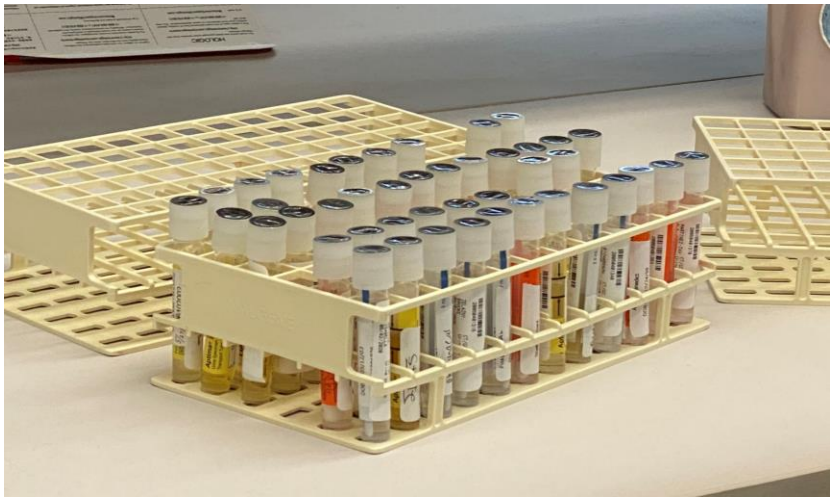


COVID-19

- 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

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

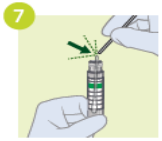
- Instructions for collecting specific types of specimens are provided by the CDC, public health departments and often by the testing laboratories.

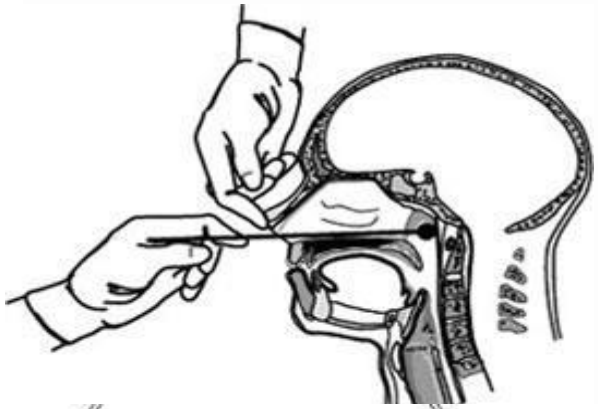
Nasopharyngeal Specimen Collection

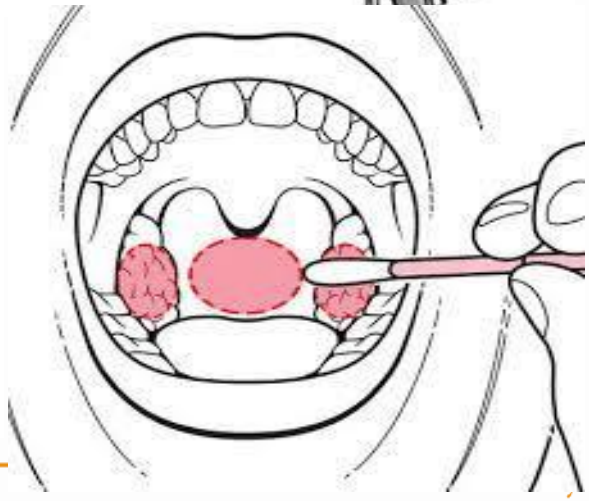
COVID-19 Testing with SARS-CoV-2-RNA, Qualitative Real-Time RT-PCR

Quest Diagnostics

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 packs/pouches must be used if placing specimens in a lockbox for courier pick-up. Specimens should be shipped overnight to your local Quest Diagnostics accessioning laboratory according to standard operating procedures. SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR test is not a STAT test and STAT pick-up cannot be ordered.





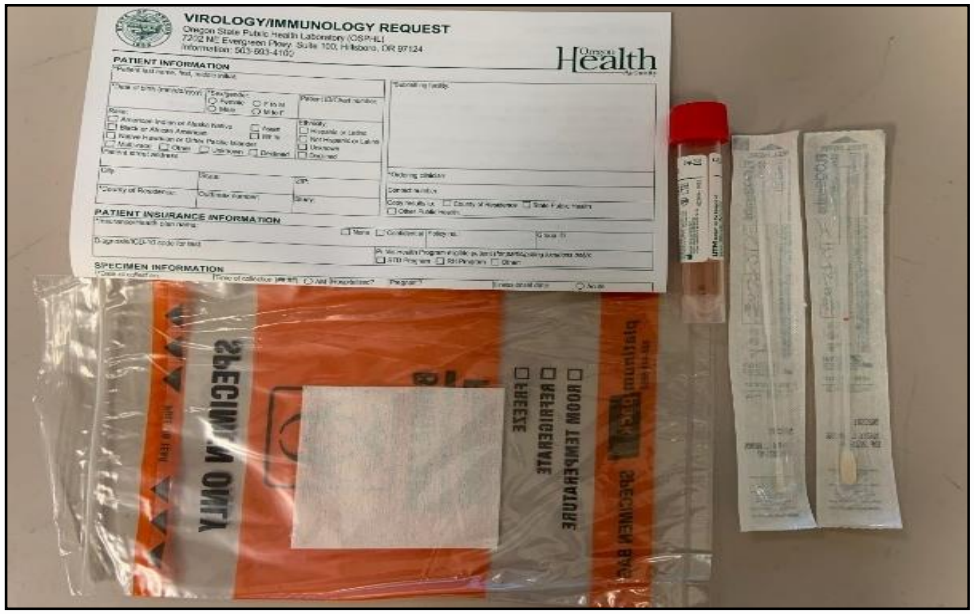
Example from Quest Diagnostic Laboratories

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



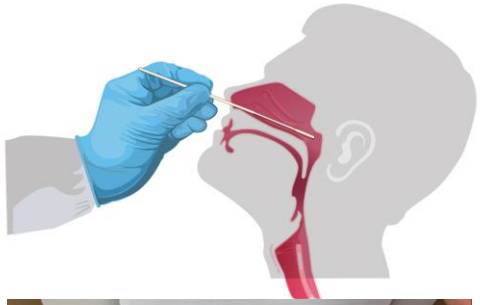
Often incorrectly referred to as a 'test kit'

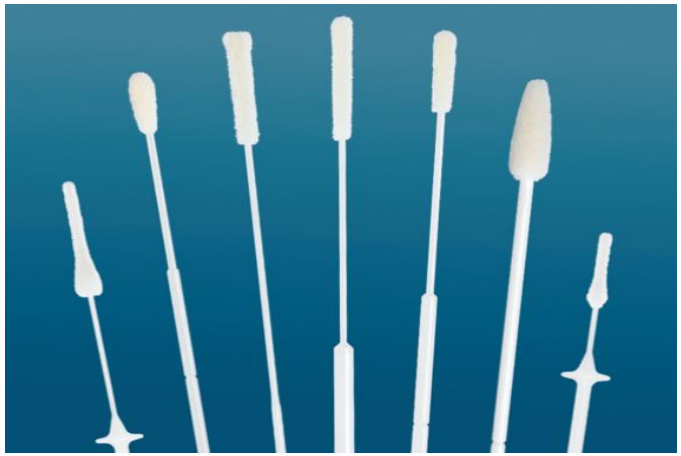
Don't forget- you will also need PPE (not pictured) to collect and handle specimens!

Oregon Health Authority

Swabs / Applicators

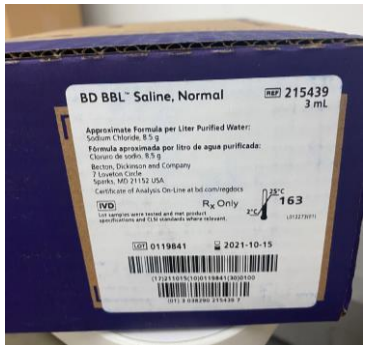
- Used to collect proper specimens such as nasopharyngeal (NP) or oropharyngeal (OP) swabs
- Various types are allowable for use for COVID lab testing
  - E.g., Flocked swabs, FLQ swabs, synthetic fibers, etc.
- Some types not allowable (e.g., calcium alginate, wood shafts)





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



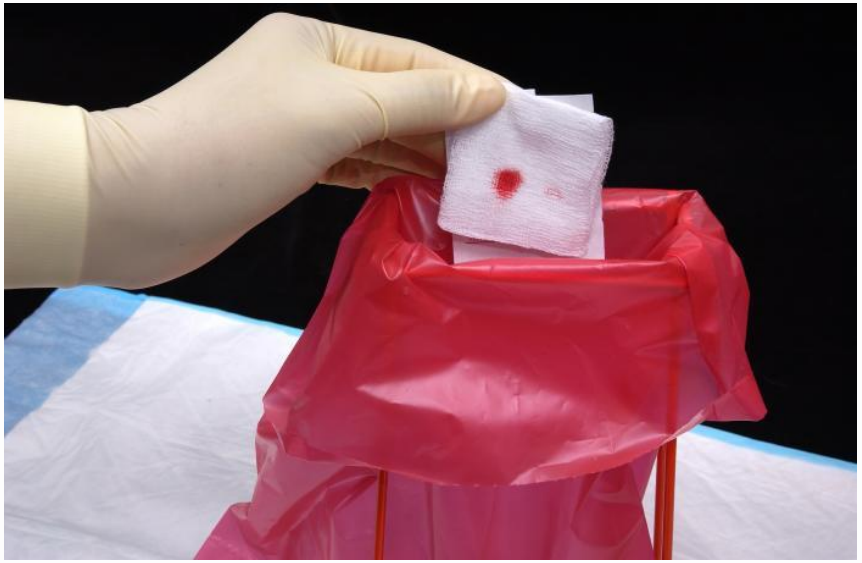
Specimen Transport Bags

- 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

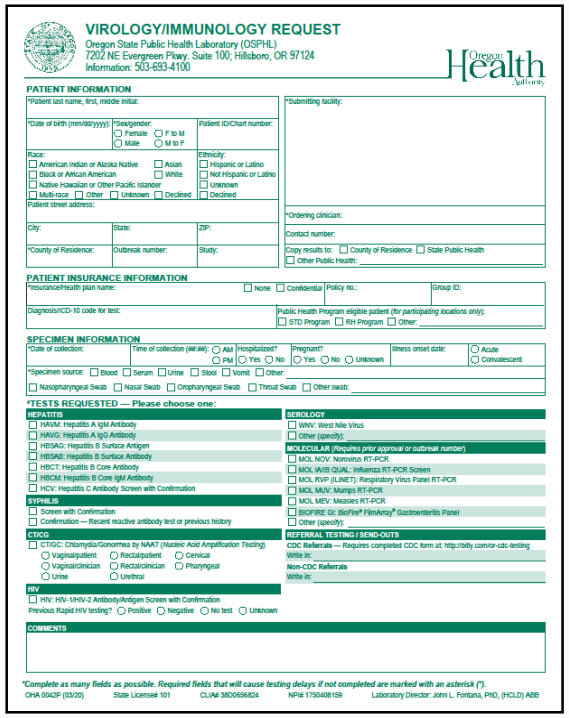
- Term typically used to describe infectious “red bag” regulated medical laboratory waste



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.)



VIROLOGY/IMMUNOLOGY REQUEST

Oregon State Public Health Laboratory (OSPHL)
7202 NE Evergreen Pkwy. Suite 100; Hillsboro, OR 97124
Information: 503-693-4100

Oregon Health Authority

PATIENT INFORMATION

*Patient last name, first, middle initial:

*Date of birth (mm/dd/yyyy):

*Sex/gender:
Female
Male
F to M
M to F

Patient ID/Chart number:

*Submitting facility:

Race:
American Indian or Alaska Native
Black or African American
Native Hawaiian or Other Pacific Islander
Multi-race
Other
Unknown
Declined

Ethnicity:
Hispanic or Latino
Not Hispanic or Latino
Unknown
Declined

Patient street address:

City:
State:
ZIP:

*County of Residence:
Outbreak number:
Study:

*Ordering clinician:
Contact number:
Copy results to:
County of Residence
State Public Health
Other Public Health:

PATIENT INSURANCE INFORMATION

*Insurance/Health plan name:
None
Confidential
Policy no.:
Group ID:

Diagnosis/ICD-10 code for test:

Public Health Program eligible patient (for participating locations only):
STD Program
RH Program
Other:

SPECIMEN INFORMATION

*Date of collection:
Time of collection (##:##):
AM
PM
Hospitalized?
Yes
No
Pregnant?
Yes
No
Unknown
Illness onset date:
Acute
Convalescent

*Specimen source:
Blood
Serum
Urine
Stool
Vomit
Other:
Nasopharyngeal Swab
Nasal Swab
Oropharyngeal Swab
Throat Swab
Other swab:

*TESTS REQUESTED — Please choose one:

HEPATITIS
HAVM: Hepatitis A IgM Antibody
HAVG: Hepatitis A IgG Antibody
HBSAG: Hepatitis B Surface Antigen
HBSAB: Hepatitis B Surface Antibody
HBCT: Hepatitis B Core Antibody
HBCM: Hepatitis B Core IgM Antibody
HCV: Hepatitis C Antibody Screen with Confirmation

SYPHILIS
Screen with Confirmation
Confirmation — Recent reactive antibody test or previous history

CT/GC
CT/GC: Chlamydia/Gonorrhea by NAAT (Nucleic Acid Amplification Testing)
Vaginal/patient
Urine
Rectal/patient
Rectal/clinician
Cervical
Pharyngeal
Urethral
Vaginal/clinician

HIV
HIV: HIV-1/HIV-2 Antibody/Antigen Screen with Confirmation
Previous Rapid HIV testing? Positive Negative No test Unknown

SEROLOGY
WNV: West Nile Virus
Other (specify):

MOLECULAR (Requires prior approval or outbreak number)
MOL NOV: Norovirus RT-PCR
MOL IAVB QUAL: Influenza RT-PCR Screen
MOL RVP (iLINET): Respiratory Virus Panel RT-PCR
MOL MUV: Mumps RT-PCR
MOL MEV: Measles RT-PCR
BIOFIRE GI: BioFire® FilmArray® Gastroenteritis Panel
Other (specify):

REFERRAL TESTING / SEND-OUTS
CDC Referrals — Requires completed CDC form at: http://bity.com/or-cdc-testing
Write in:
Non-CDC Referrals
Write in:

COMMENTS

*Complete as many fields as possible. Required fields that will cause testing delays if not completed are marked with an asterisk (*).

OHA 0042P (03/20) State License# 101 CLIA# 38D0656824 NPI# 1750408199 Laboratory Director: John L. Fontana, PhD, (HCLD) ABB

- 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

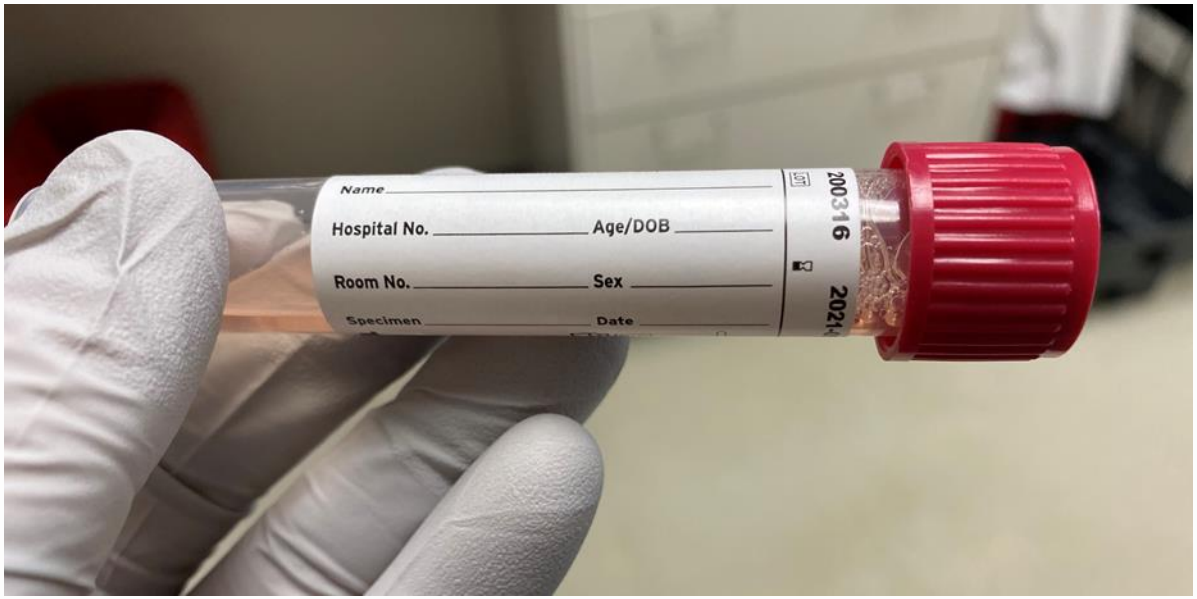
Specimen Handling

- 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

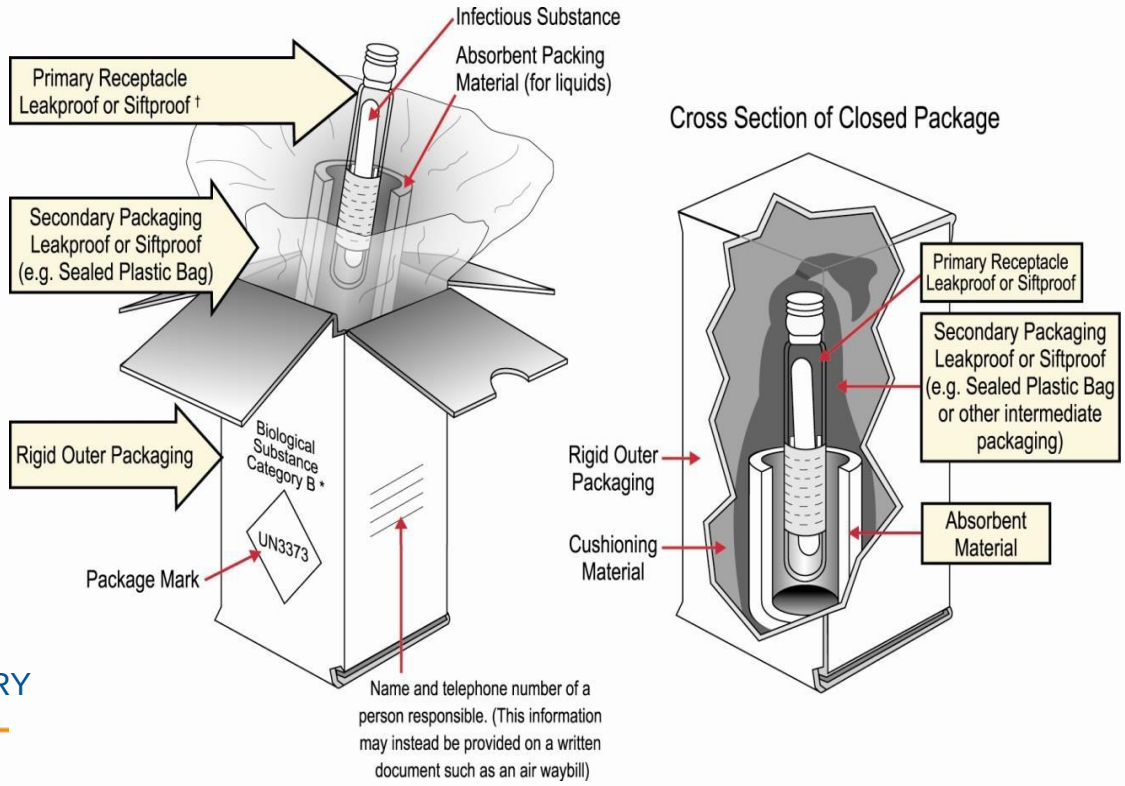
- Store collected specimens at the same temperature they will need to be at for shipping/transport to testing lab.
  - Always consult with the testing lab for specimen shipping temperature requirements
  - Specimen shipping temperature will depend on ***when*** the samples will be tested
- Store specimens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

Testing Guidelines

- **Outline testing requirements and recommendations.**
- CDC Testing Guidelines
  - https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html
- OHA Testing Guidelines
  - 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
  - https://www.cms.gov/regulations-and-guidance/legislation/clia/index.html
  - https://www.cdc.gov/clia/law-regulations.html

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Clinical Laboratory Improvement Amendments

Oregon Health Authority

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

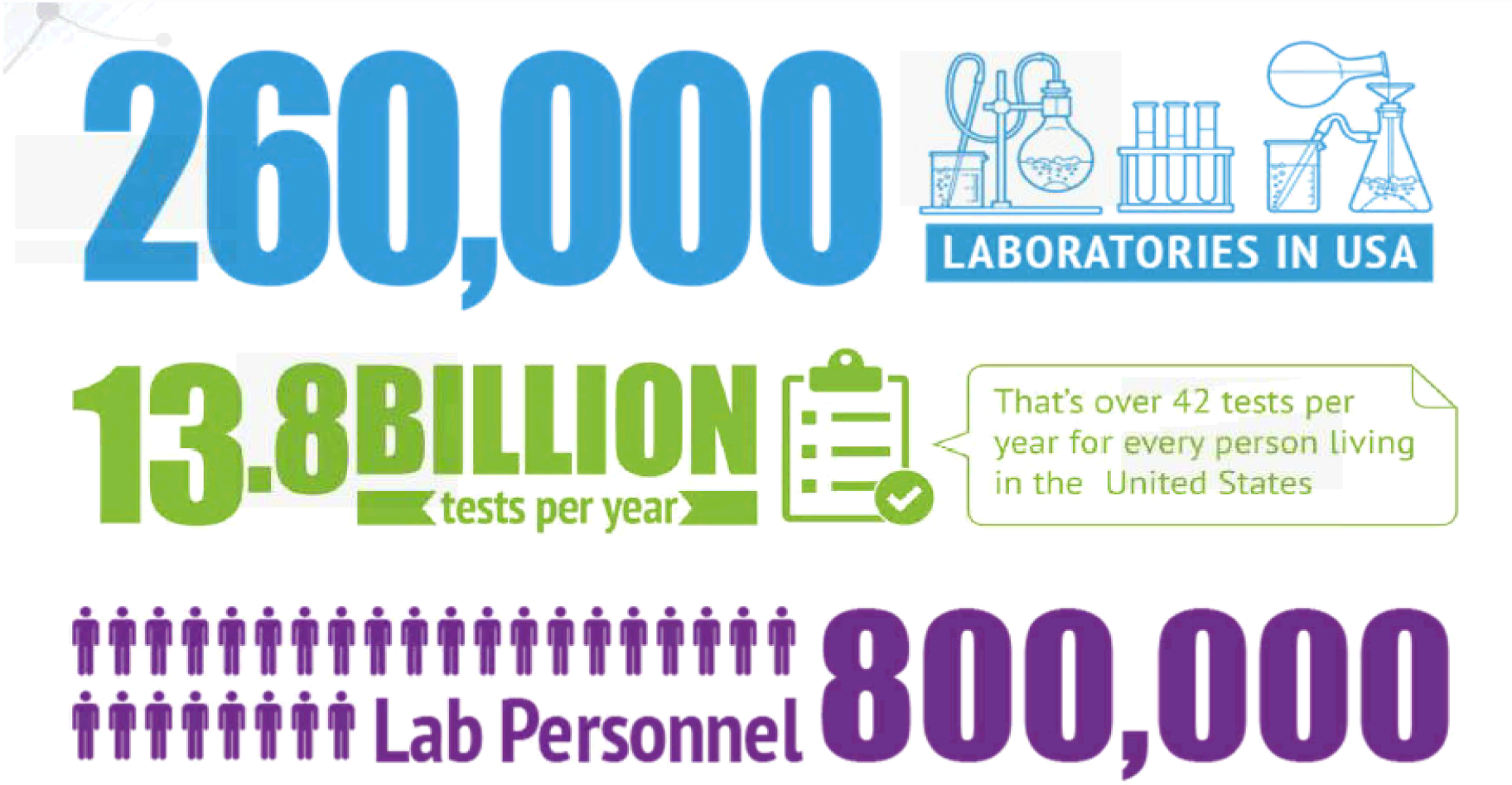
- The more complicated the test, the more stringent the specific CLIA quality standards and requirements are for personnel qualifications and responsibilities.

  Waived → Moderate Complexity → High Complexity

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

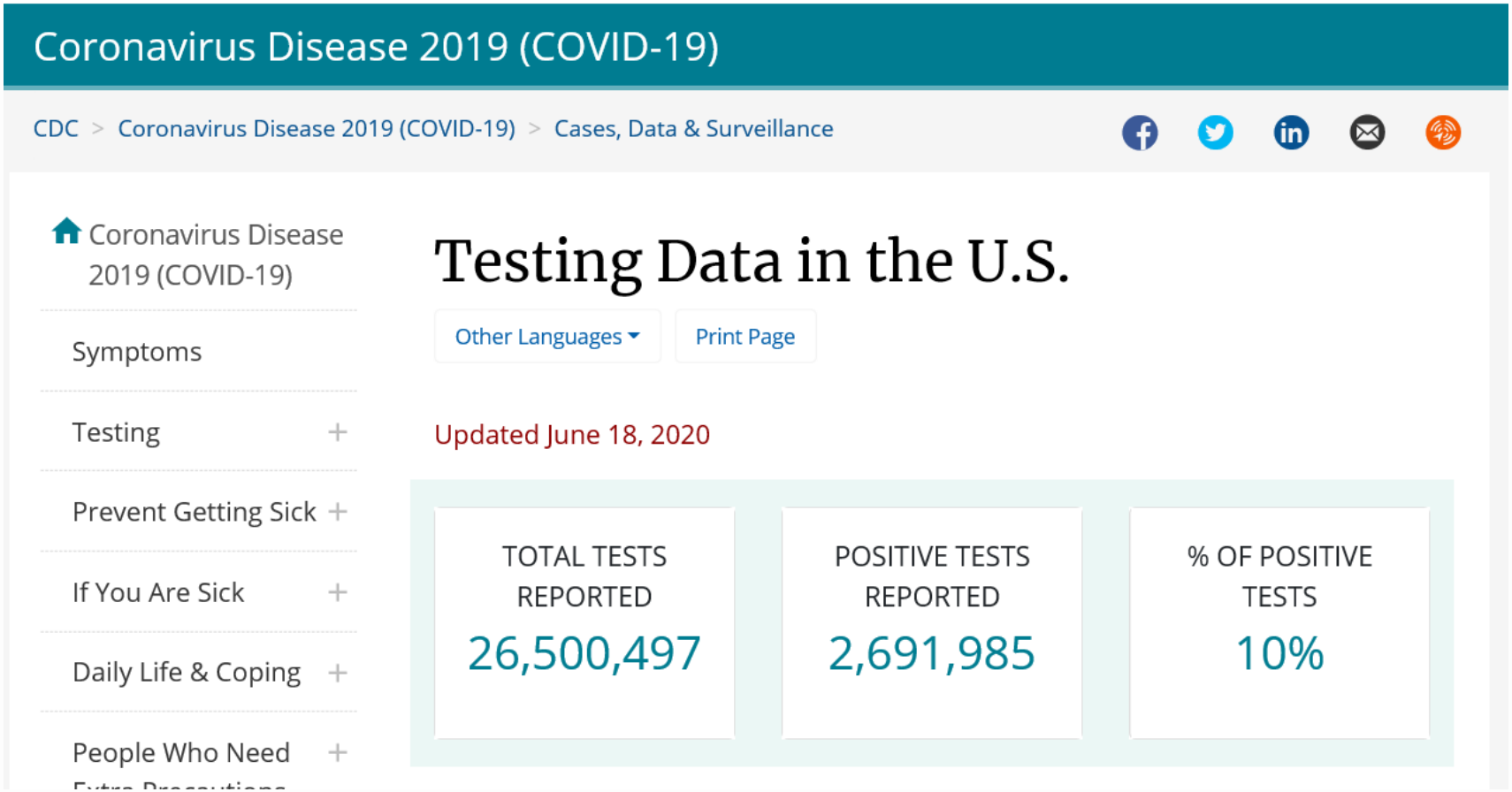
https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincliacertificate.pdf

US Clinical Laboratory Community



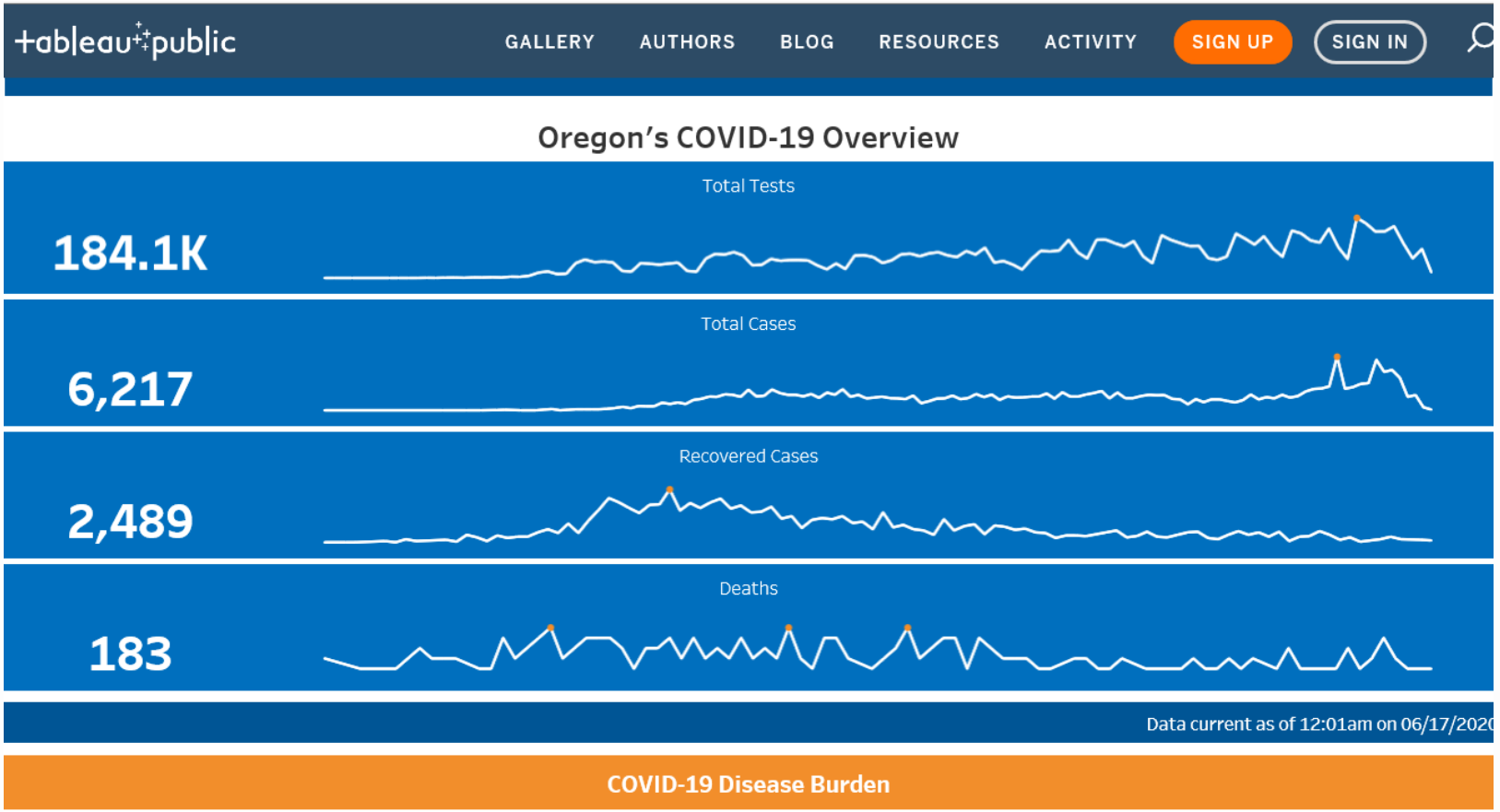
https://www.cdc.gov/CSELS/dls/

CDC Laboratory Testing Data



https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/testing-in-us.html

OHA Testing Overview



https://public.tableau.com/profile/oregon.health.authority.covid.19#!/vizhome/OregonCOVID-19PublicHealthIndicators/COVID-19Burden

OHA Testing Information

Oregon Health Authority
PUBLIC HEALTH DIVISION

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

https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/le2279a.pdf

SARS-CoV-2 / COVID-19 Lab Tests

- FDA Emergency Use Authorization (EUA) website lists currently authorized medical devices, PPE, and in vitro diagnostics
  - https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

- 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

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

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

Accula SARS CoV-2
https://www.mesabiotech.com/coronavirus

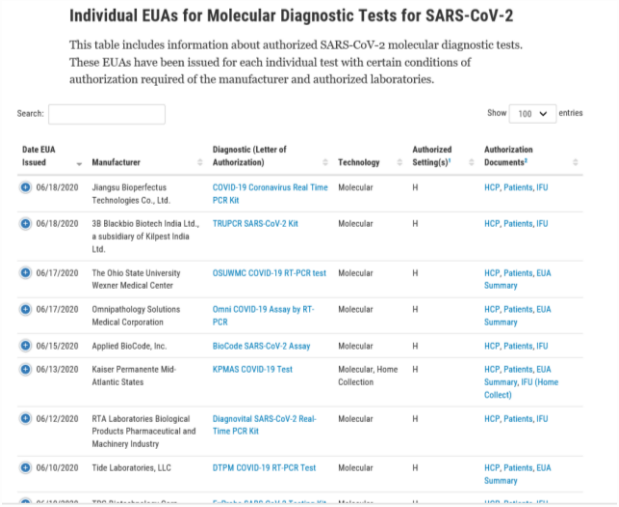
Moderate and High Complexity Testing

- 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!!!



Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2

This table includes information about authorized SARS-CoV-2 molecular diagnostic tests. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories.

Search: Show 100 entries

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
06/18/2020	Jiangsu Bioperfectus Technologies Co., Ltd.	COVID-19 Coronavirus Real Time PCR Kit	Molecular	H	HCP, Patients, IFU
06/18/2020	3B Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd.	TRUPCR SARS-CoV-2 Kit	Molecular	H	HCP, Patients, IFU
06/17/2020	The Ohio State University Wexner Medical Center	OSUWMC COVID-19 RT-PCR test	Molecular	H	HCP, Patients, EUA Summary
06/17/2020	Omnipathology Solutions Medical Corporation	Omni COVID-19 Assay by RT-PCR	Molecular	H	HCP, Patients, EUA Summary
06/15/2020	Applied BioCode, Inc.	BioCode SARS-CoV-2 Assay	Molecular	H	HCP, Patients, IFU
06/13/2020	Kaiser Permanente Mid-Atlantic States	KPMAS COVID-19 Test	Molecular, Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collect)
06/12/2020	RTA Laboratories Biological Products Pharmaceutical and Machinery Industry	Diagnovital SARS-CoV-2 Real-Time PCR Kit	Molecular	H	HCP, Patients, IFU
06/10/2020	Tide Laboratories, LLC	DTPM COVID-19 RT-PCR Test	Molecular	H	HCP, Patients, EUA Summary

06/10/2020	Tide Laboratories, LLC	DTPM COVID-19 RT-PCR Test	Molecular	H	HCP, Patients, EUA Summary
06/10/2020	TBG Biotechnology Corp.	ExProbe SARS-CoV-2 Testing Kit	Molecular	H	HCP, Patients, IFU
06/10/2020	Cue Health Inc.	Cue COVID-19 Test	Molecular	H, M, W	HCP, Patients, IFU
06/09/2020	Illumina, Inc.	Illumina COVIDSeq Test	Molecular	H	HCP, Patients, IFU
06/09/2020	ChromaCode Inc.	HDPCR SARS-CoV-2 Assay	Molecular	H	HCP, Patients, IFU
06/08/2020	Euroimmun US, Inc.	EURORealTime SARS-Cov-2	Molecular	H	HCP, Patients, IFU
06/05/2020	Genetron Health (Beijing) Co., Ltd.	Genetron SARS-CoV-2 RNA Test	Molecular	H	HCP, Patients, IFU
06/04/2020	Phosphorus Diagnostics LLC	Phosphorus COVID-19 RT-qPCR Test	Molecular, Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collect), IFU (Clinic)
06/01/2020	Gravity Diagnostics, LLC	Gravity Diagnostics COVID-19 Assay	Molecular	H	HCP, Patients, EUA Summary
05/28/2020	PrivaPath Diagnostics, Inc.	LetsGetChecked Coronavirus (COVID-19) Test	Molecular, Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collect)
05/22/2020	dba SpectronRX	Hymon SARS-CoV-2 Test Kit	Molecular	H	HCP, Patients, IFU
05/21/2020	P23 Labs, LLC.	P23 Labs TaqPath SARS-CoV-2 Assay	Molecular, Home Collection	H	HCP, Patients, IFU (Home Collect), EUA Summary
05/21/2020	Seasun Biomaterials, Inc.	AQ-TOP COVID-19 Rapid Detection Kit	Molecular	H	HCP, Patients, IFU
05/21/2020	SolGent Co., Ltd	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit	Molecular	H	HCP, Patients, IFU
05/21/2020	BioCore Co., Ltd.	BioCore 2019-nCoV Real Time PCR Kit	Molecular	H	HCP, Patients, IFU
05/18/2020	Quidel Corporation	Lyra Direct SARS-CoV-2 Assay	Molecular	H	HCP, Patients, IFU

					Collect)
05/15/2020	Everlywell, Inc.	Everlywell COVID-19 Test Home Collection Kit	Home Collection Kit	N/A	IFU, EUA Summary
05/15/2020	Assurance Scientific Laboratories	Assurance SARS-CoV-2 Panel	Molecular	H	HCP, Patients, EUA Summary
05/14/2020	Hologic, Inc.	Aptima SARS-CoV-2 assay	Molecular	H	HCP, Patients, IFU
05/14/2020	GeneMatrix, Inc.	NeoPlex COVID-19 Detection Kit	Molecular	H	HCP, Patients, IFU
05/13/2020	Applied DNA Sciences, Inc.	Linea COVID-19 Assay Kit	Molecular	H	HCP, Patients, IFU
05/11/2020	1drop Inc.	1copy COVID-19 qPCR Multi Kit	Molecular	H	HCP, Patients, IFU
05/11/2020	Abbott Molecular Inc.	Alinity m SARS-CoV-2 assay	Molecular	H, M	HCP, Patients, IFU
05/08/2020	Gnomegen LLC	Gnomegen COVID-19-RT-qPCR Detection Kit	Molecular	H	HCP, Patients, IFU
05/07/2020	Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics - Rutgers University	Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay	Molecular, Home Collection	H	HCP, Patients, IFU (Home Collect), EUA Summary
05/07/2020	Zymo Research Corporation	Quick SARS-CoV-2rRT-PCR Kit	Molecular	H	HCP, Patients, IFU
05/06/2020	OPTI Medical Systems, Inc.	OPTI SARS-CoV-2 RT PCR Test	Molecular	H	HCP, Patients, IFU
05/06/2020	Sherlock BioSciences, Inc.	Sherlock CRISPR SARS-CoV-2 Kit	Molecular	H	HCP, Patients, IFU
05/06/2020	BioMérieux SA	SARS-COV-2 R-GENE	Molecular	H	HCP, Patients, IFU
05/05/2020	Fast Track Diagnostics Luxembourg S.à.r.l. (a Siemens Healthineers Company)	FTD SARS-CoV-2	Molecular	H	HCP, Patients, IFU
05/04/2020	Sansure BioTech Inc.	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	Molecular	H	HCP, Patients, IFU
05/01/2020	Bio-Rad Laboratories, Inc	Bio-Rad SARS-CoV-2 ddPCR Test	Molecular	H	HCP, Patients, IFU

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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.

https://www.aphl.org/aboutAPHL/publications/Documents/PHPR_SurgeCapacityLRNB_JAN2015.pdf

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.

https://www.aphl.org/aboutAPHL/publications/Documents/PHPR_SurgeCapacityLRNB_JAN2015.pdf

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.

https://www.aphl.org/aboutAPHL/publications/Documents/PHPR_SurgeCapacityLRNB_JAN2015.pdf

Factors Affecting Surge Capacity

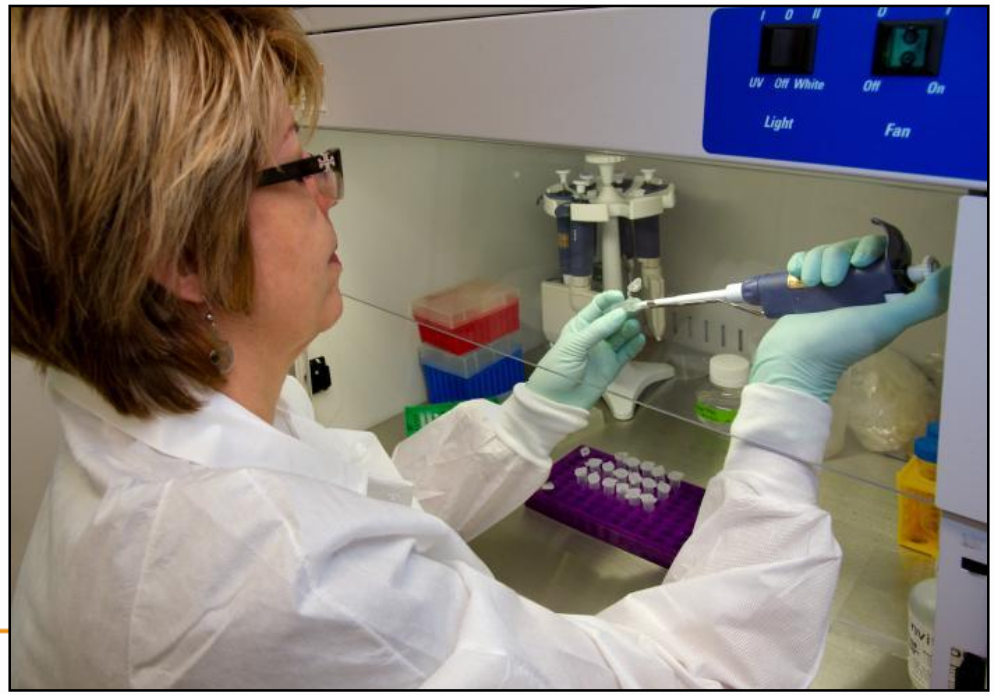
- ***Infrastructure Factors:***
  - BSL-2 and BSL-3 facilities and total laboratory bench space
  - Biological safety cabinets and chemical fume hoods
  - Reagent supply (amount, type, expiration date) and access to additional/different reagents
  - Analytical equipment (PCR, MALDI-TOF, GC/MS, LC/MS, 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
  - https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html
  - https://www.cdc.gov/media/releases/2020/p0604-new-lab-data-reporting.html

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.

GUIDANCE ON

INTERPRETING COVID-19 TEST RESULTS

	RESULT	INTERPRETATION	RECOMMENDED ACTION
VIRAL TESTING† (testing for current infection)	**Positive**	*Most likely** you DO currently have an active COVID-19 infection and can give the virus to others.	Stay home* and follow CDC guidance on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.
	Negative	*Most likely** you DO NOT currently have an active COVID-19 infection.	If you have symptoms, you should keep monitoring symptoms and seek medical advice about staying home and if you need to get tested again. If you don't have symptoms, you should get tested again only if your medical provider and/or workplace tells you to. Take steps to protect yourself and others.
ANTIBODY TESTING‡ (testing for past infection with the virus)	**Positive**‡	You *likely** have HAD a COVID-19 infection.	You may be protected from re-infection (have immunity), but this cannot be said with certainty. Scientists are conducting studies now to provide more information. Take steps to protect yourself and others.
	Negative	You *likely** NEVER HAD (or have not yet developed antibodies to) COVID-19 infection.	You could still get COVID-19. Take steps to protect yourself and others.
BOTH (antibody and viral testing)	Viral **Positive**, Antibody **Positive**‡	*Most likely** you DO currently have an active COVID-19 infection and can give the virus to others.	Stay home* and follow CDC guidance on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.
	Viral **Positive**, Antibody **Negative**	*Most likely** you DO currently have an active COVID-19 infection and can give the virus to others.	Stay home* and follow CDC guidance on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.
	Viral **Negative**, Antibody **Positive**	You *likely** have HAD and RECOVERED FROM a COVID-19 infection.	You may be protected from re-infection (have immunity), but this cannot be said with certainty. Scientists are conducting studies now to provide more information. You should get tested again only if your medical provider and/or workplace tells you to. Take steps to protect yourself and others.
	Viral **Negative**, Antibody **Negative**	You *likely** have NEVER HAD a COVID-19 infection.	You could still get COVID-19. You should get tested again only if your medical provider and/or workplace tells you to. Take steps to protect yourself and others.

*No test is ever perfect. All tests occasionally result in false positive results (the test result should be negative because you DO NOT have COVID-19 but comes back positive) or false negative results (the test result should be positive because you DO have COVID-19, but comes back negative). Sometimes the results are not definitive (the result is unclear, and you don't know if it is positive or negative). For this and other reasons, results should always be reviewed by a healthcare professional.

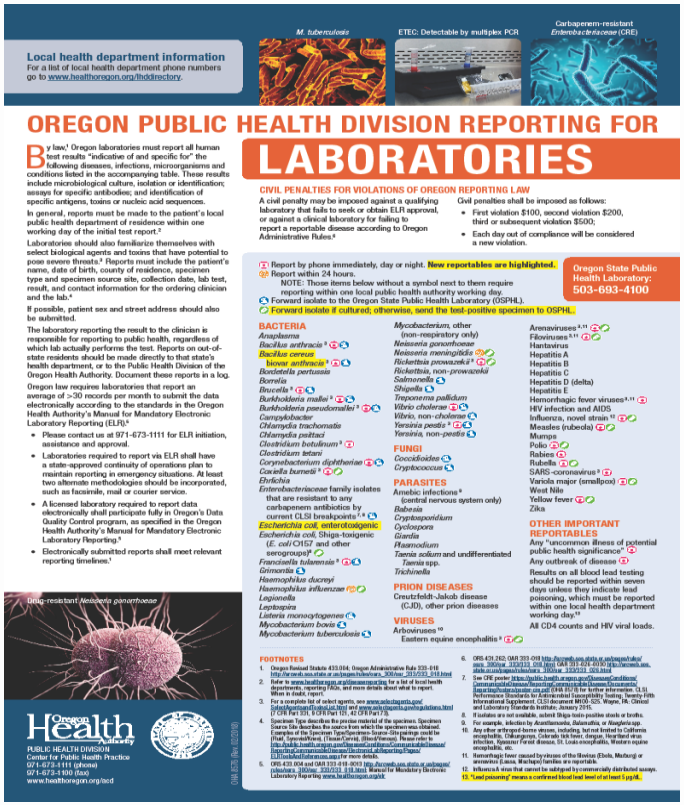
†Viral tests are typically performed on respiratory specimens such as nasal swabs or throat swabs. They test for the presence of the virus, usually by testing for the virus's RNA or sometimes by testing for the virus's proteins ("antigen testing"). Antigen testing may be less sensitive than tests for the virus's RNA. If your antigen test is negative, please ask your healthcare provider if additional testing with an RNA test is needed and how long you should stay home.

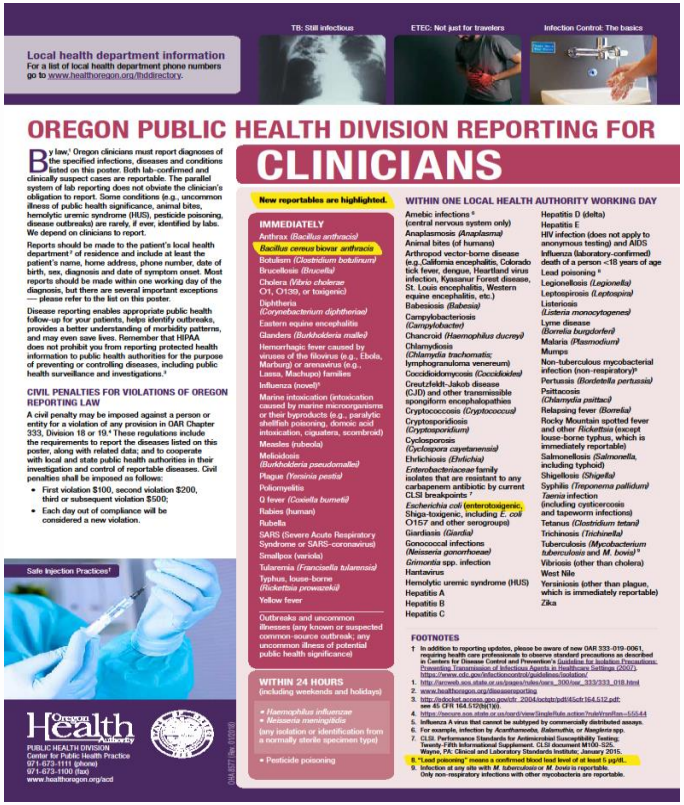
‡Antibody testing, also called "serologic testing" or "serology", is typically performed on a blood sample. Ideally, the results show whether you have ever been infected with the virus in the past or may be currently infected. Antibody tests check for antibodies that appear in the blood between about one and three weeks after symptom onset and may remain as long as a lifetime. Antibody tests may be positive while a person is infected. It is not yet known whether these antibodies protect against reinfection with the COVID-19 virus. For many other similar viruses, antibodies are protective for years or longer, but we do not yet have adequate data to know for COVID-19.

https://www.whitehouse.gov/wp-content/uploads/2020/05/Testing-Guidance.pdf

OHA Disease Reporting

- Notifiable diseases and conditions that must be reported to public health from laboratories and clinicians www.healthoregon.org/diseasereporting





PUBLIC HEALTH DIVISION
OREGON STATE PUBLIC HEALTH LABORATORY

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/ehrmeaningfuluse/elr.html
- OHA ELR Information
  - 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.

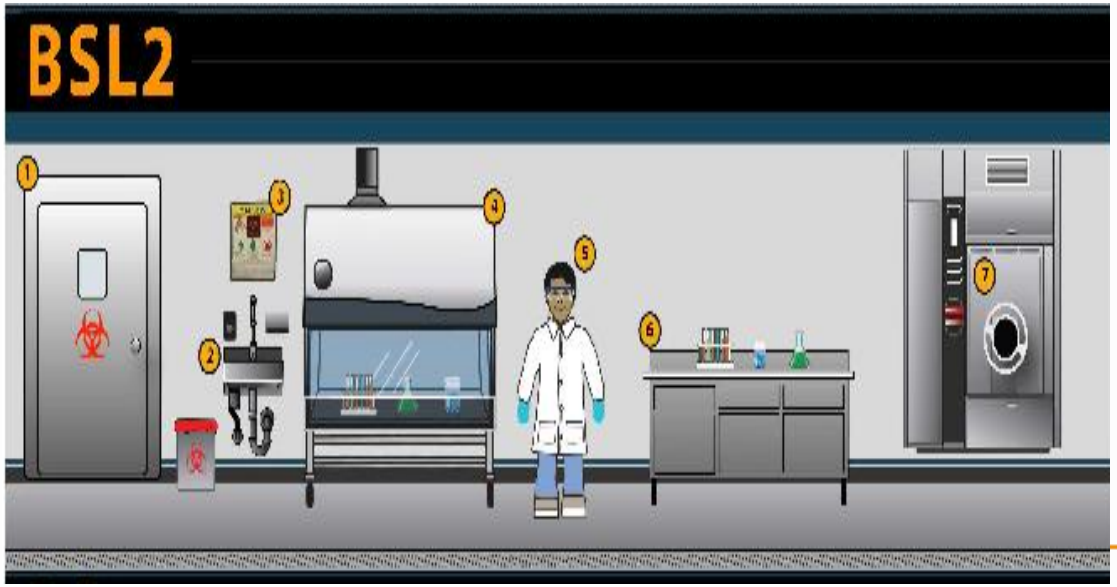
- CDC Standard Precaution Info:
  - https://www.cdc.gov/oralhealth/infectioncontrol/summary-infection-prevention-practices/standard-precautions.html

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



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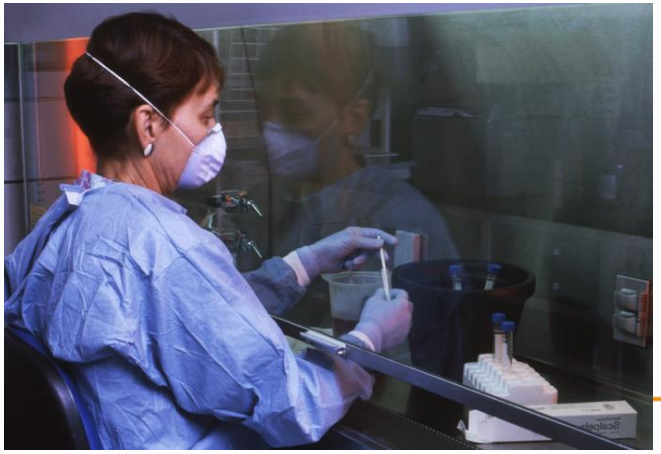
Administrative Controls

- 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



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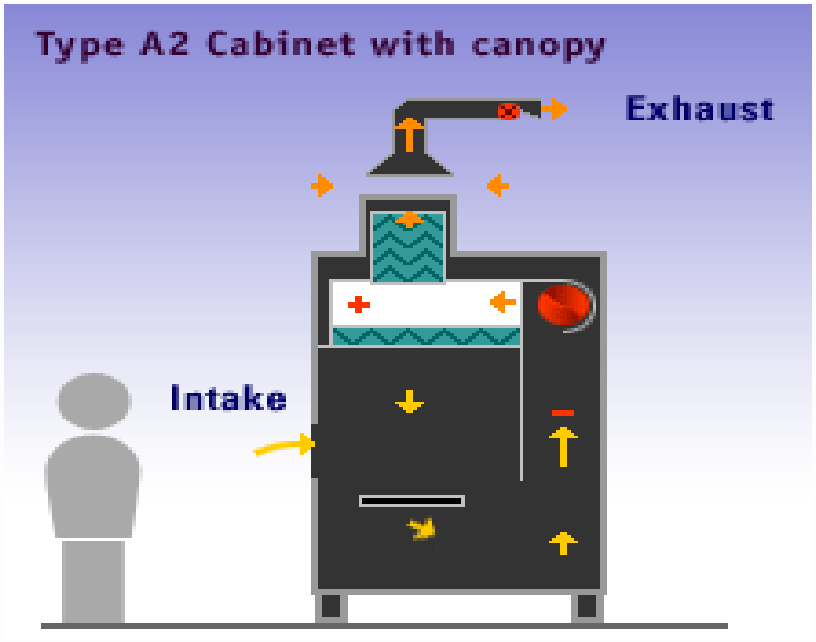
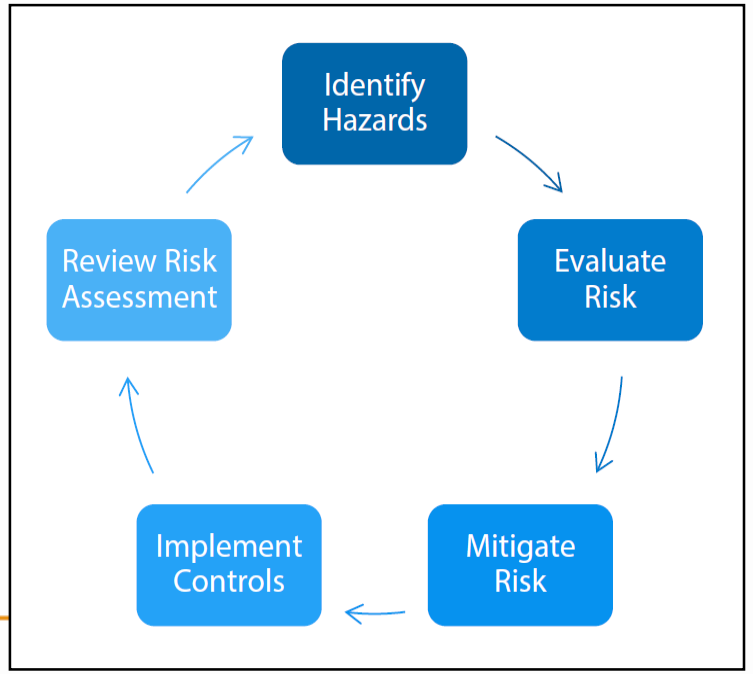
Biological Safety Cabinet (BSC)

- 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.



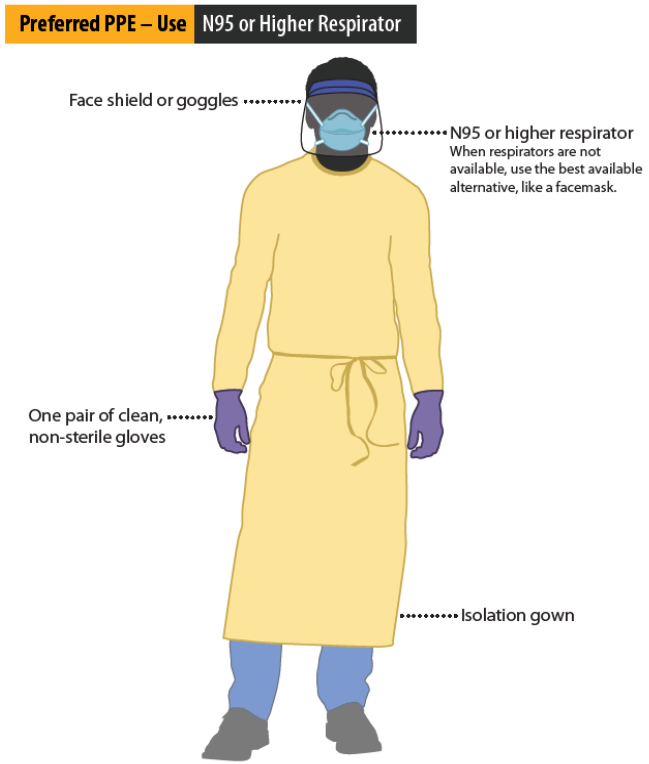
Biological Risk Assessment

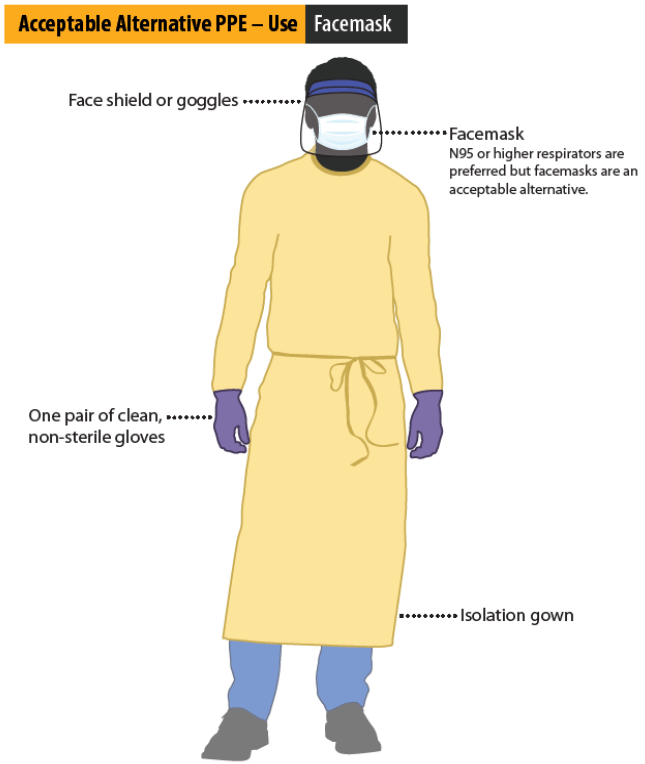
- All laboratories should routinely perform a site-specific and activity-specific risk assessment to identify and mitigate risks.
- Risk assessments and mitigation measures are dependent on:
  - The procedures performed
  - Identification of the hazards involved in the process and/or procedures
  - The 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.





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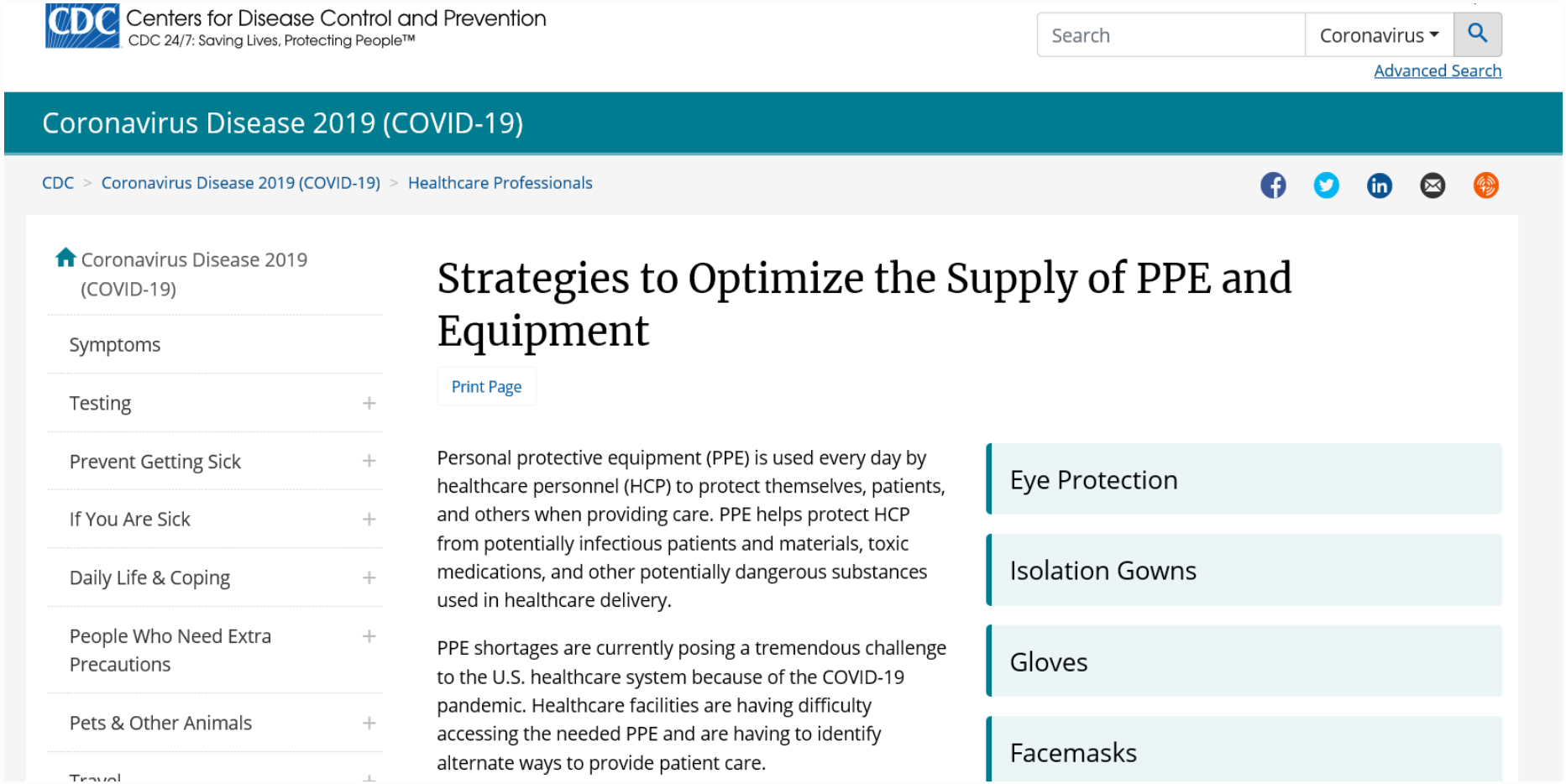
PPE Optimization Strategies



https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html

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

	 Surgical Mask	 N95 Respirator
Testing and Approval	Cleared by the U.S. Food and Drug Administration (**FDA**)	Evaluated, tested, and approved by **NIOSH** as per the requirements in 42 CFR Part 84
Intended Use and Purpose	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.	Reduces wearer's exposure to particles including small particle aerosols and large droplets (**only non-oil aerosols**).
Face Seal Fit	Loose-fitting	Tight-fitting
Fit Testing Requirement	No	Yes
User Seal Check Requirement	No	Yes. Required each time the respirator is donned (put on)
Filtration	Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection	Filters out at least 95% of airborne particles including large and small particles
Leakage	Leakage occurs around the edge of the mask when user inhales	When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales
Use Limitations	Disposable. Discard after each patient encounter.	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.

CDC NIOSH Centers for Disease Control and Prevention National Institute for Occupational Safety and Health

The CDC & NIOSH have developed several respiratory guidance materials:

https://www.cdc.gov/niosh/npptl/pdfs/UnderstandDifferenceInfographic-508.pdf

https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html

https://www.cdc.gov/niosh/npptl/respirators/testing/default.html

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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
https://www.epa.gov/coronavirus/disinfectant-use-and-coronavirus-covid-19

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

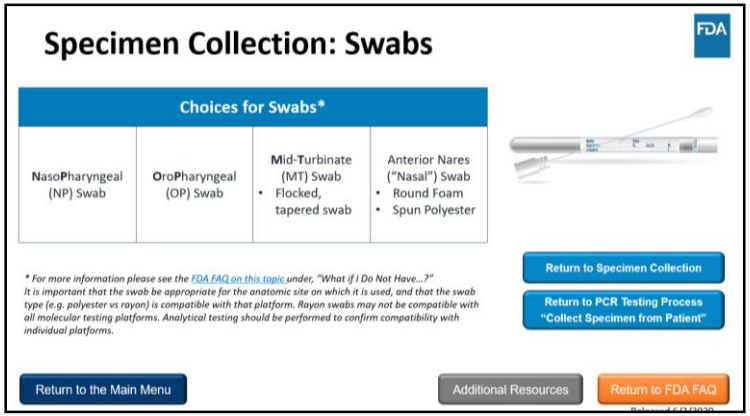
- ***Cleaning*** is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products.
- Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of the processes.

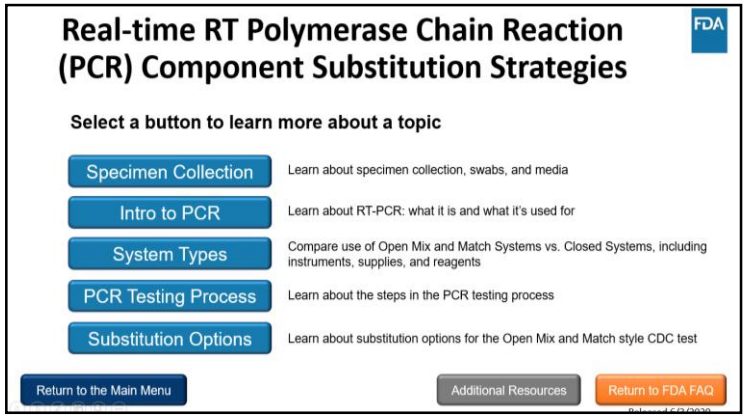
Antiseptic

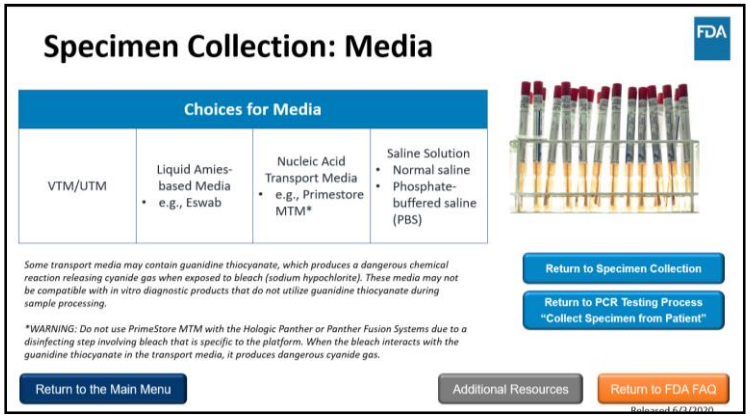
- Substance that prevents or arrests the growth or action of microorganisms by inhibiting their activity or by destroying them.
- The term is used especially for preparations applied topically to living tissue.

FDA Testing Supply Guidance

- The FDA provides a great resource that describes testing procedures, processes and materials
  - https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2







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
  - https://www.cdc.gov/coronavirus/2019-ncov/index.html
- CDC Information for Laboratories about COVID-19
  - https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html
- CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19
  - https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html
- CDC Interim Guidelines for Biosafety and COVID-19
  - https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html
- CDC COVID-19 Testing Overview
  - https://www.cdc.gov/coronavirus/2019-ncov/testing/index.html

Biosafety Resources and References

- CDC Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories
  - https://www.cdc.gov/MMWR/pdf/other/su6101.pdf
- WHO Laboratory Biosafety Guidance Related to the Novel Coronavirus (2019 nCoV)
  - https://www.who.int/docs/default-source/coronaviruse/laboratory-biosafety-novel-coronavirus-version-1-1.pdf?sfvrsn=912a9847_2
- CDC Interim Guidelines for Biosafety and COVID-19
  - https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html
- APHL Risk Assessment Best Practices
  - https://www.aphl.org/programs/preparedness/Documents/APHL%20Risk%20Assessment%20Best%20Practices%20and%20Examples.pdf
- 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
  - https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2
- FDA Emergency Use Authorizations (EUAs)
  - https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations
- CDC COVID-19 Testing Info
  - https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html
- CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19
  - https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html
- OHA Testing Guidelines
  - www.healthoregon.org/coronavirushcp

CLIA Resources & References

CLIA Law & Regulations

- https://www.cdc.gov/clia/law-regulations.html
- https://www.cms.gov/regulations-and-guidance/legislation/clia/index

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

- https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincliacertificate.pdf

CLIA Categorization

- https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clia-categorizations
- https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Categorization_of_Tests.html

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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