CDC Guidelines for Collecting and Handling Clinical Specimens for COVID-19

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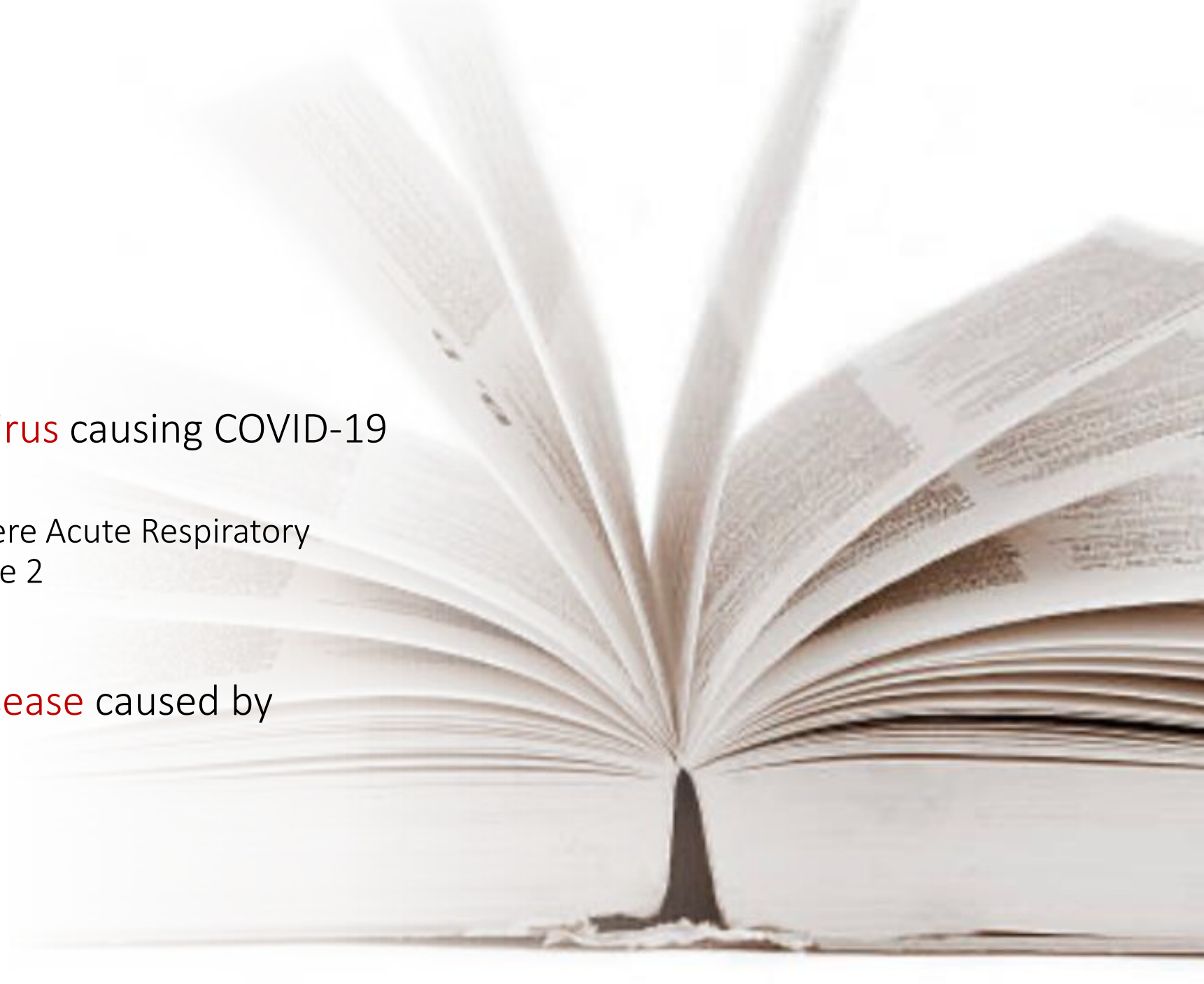
Glossary of Terms

- **SARS-CoV2**: Name of the virus causing COVID-19 disease
  - Abbreviation stands for Severe Acute Respiratory Syndrome, Corona Virus type 2

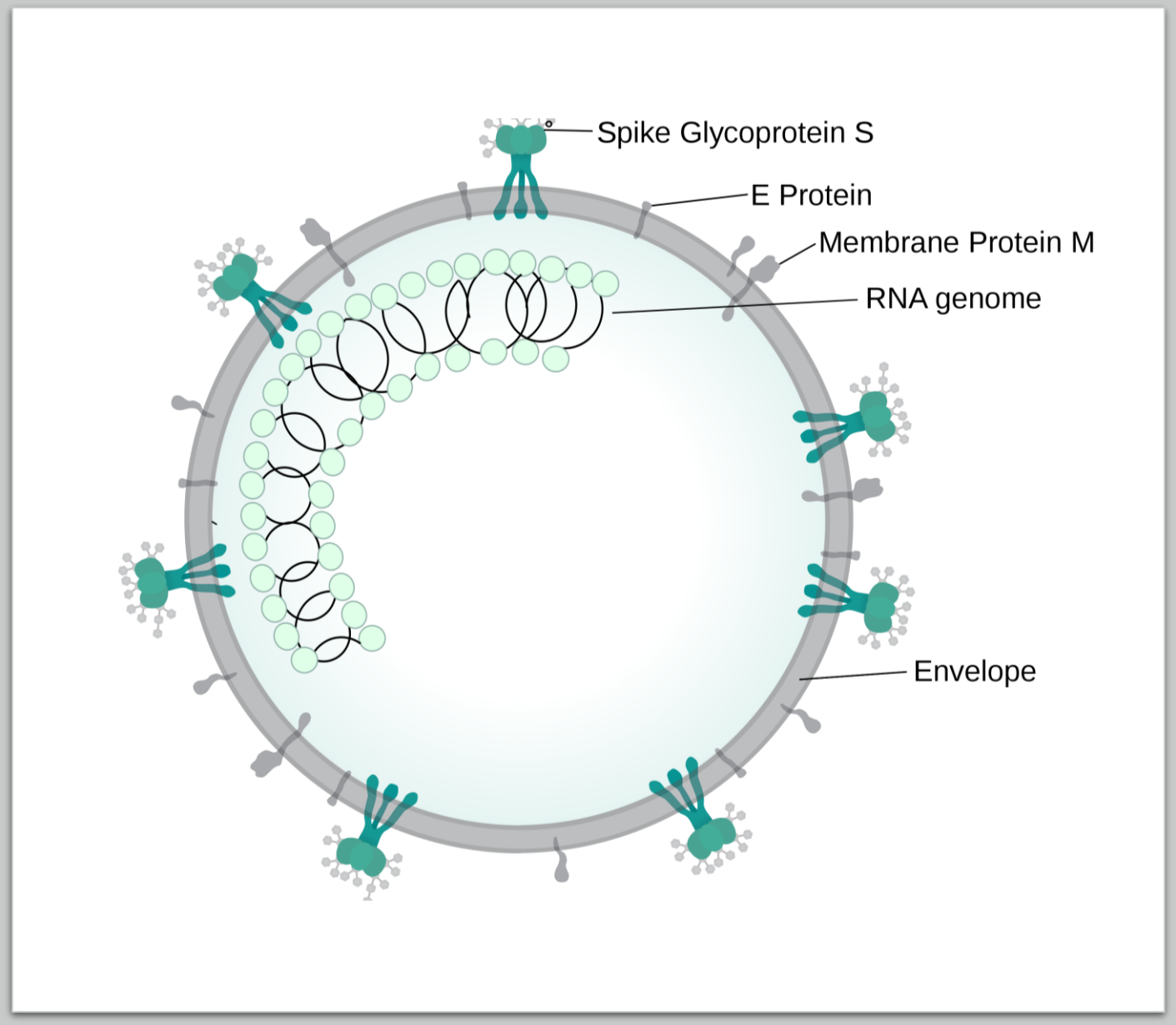
- **COVID-19**: Name of the disease caused by SARS-CoV2 virus

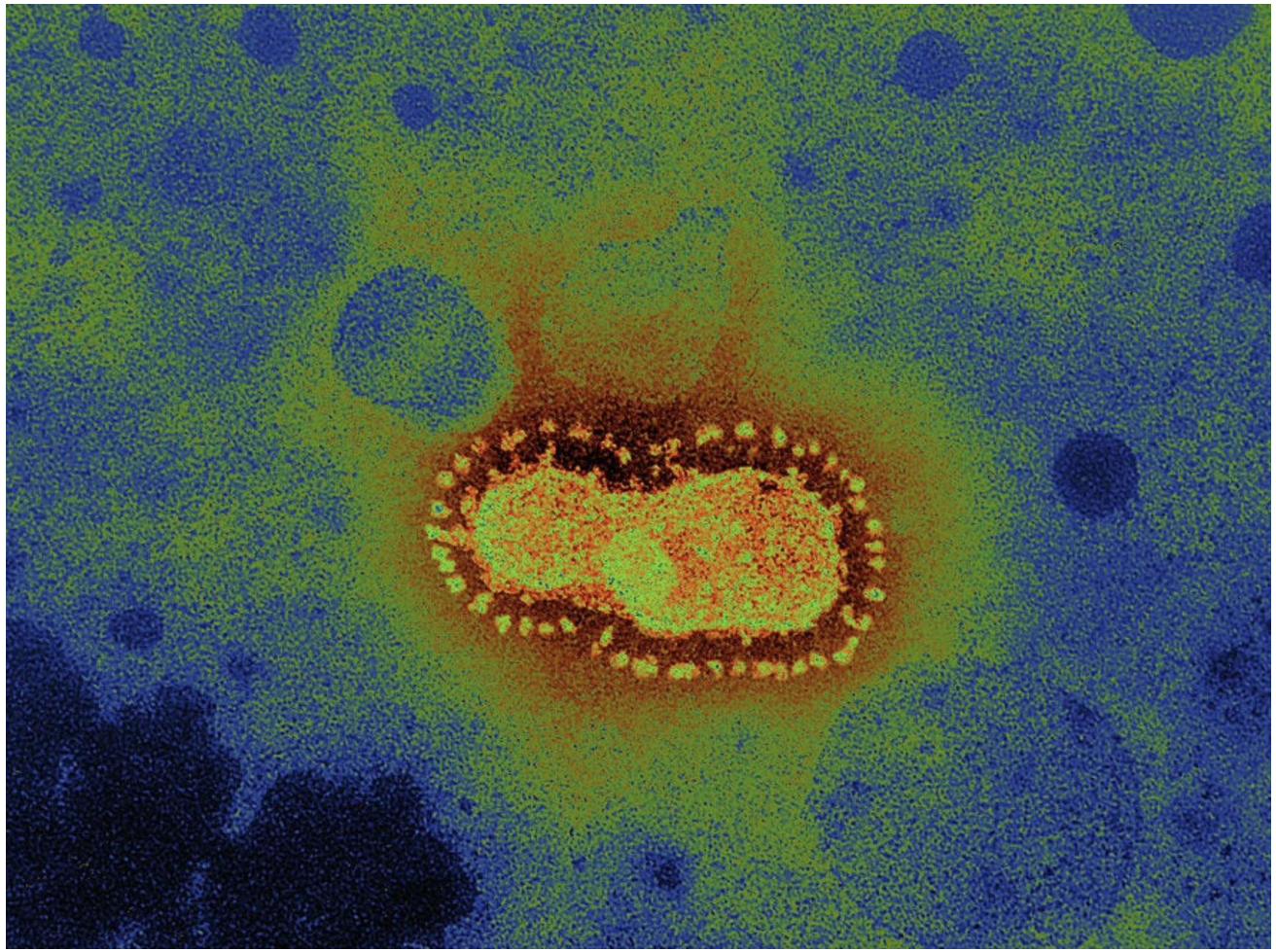


Corona from *L. corōna*

Crown

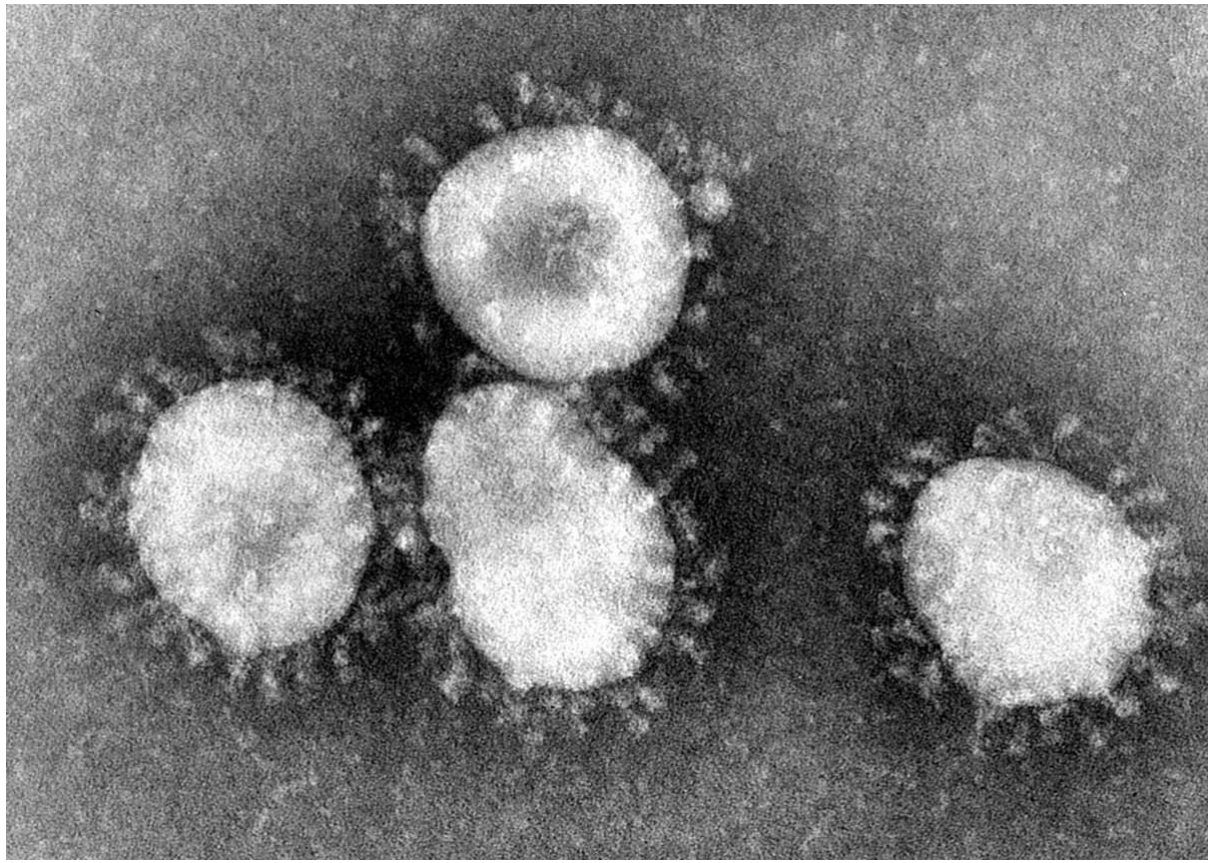
The coronavirus' crown-like spikes give the virus family its name





BSIP/UIG Via Getty Images

Transmission electron micrograph of a Coronavirus

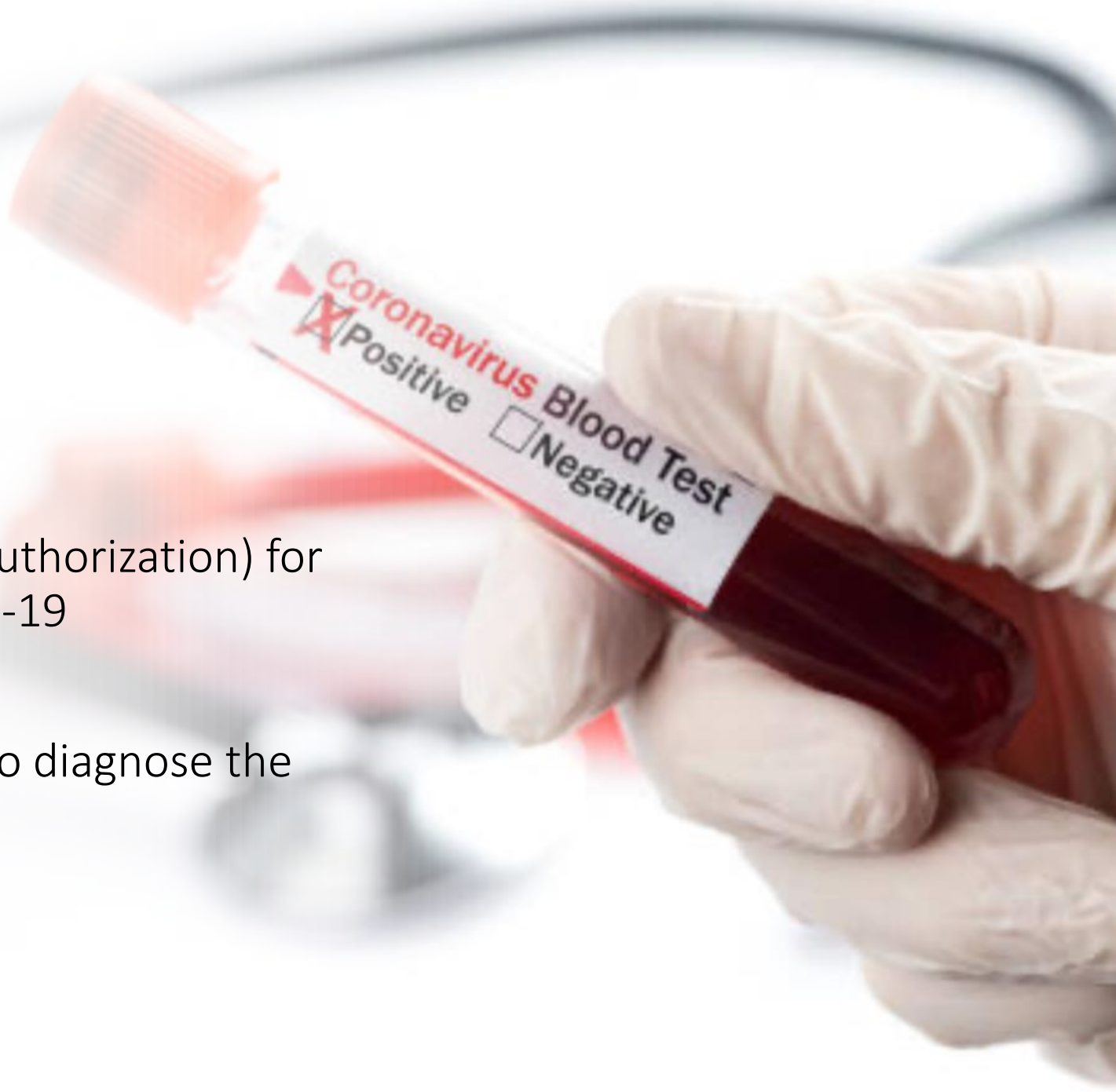


Healthcare providers considering testing for COVID-19

- Should work with state and local health depts.
  - coordinate testing through public, commercial, or clinical laboratories using viral tests granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA)

- CDC provides guidance for who should be tested, but such decisions are made at the discretion of state, and health departments (local, tribal), and/or healthcare providers.

Viral or Antibody test



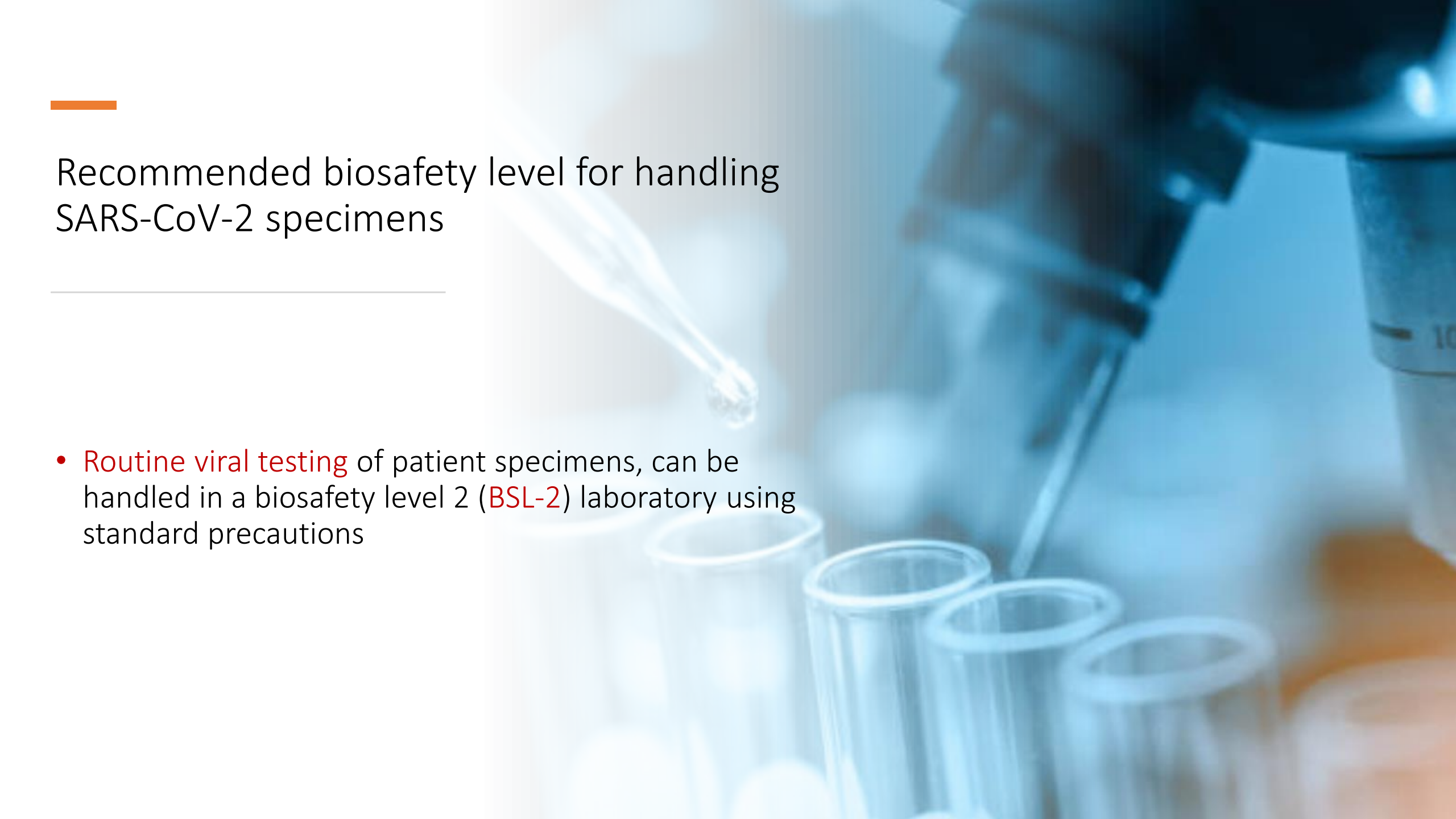
- FDA approved EUAs (Emergency Use Authorization) for both viral and antibody tests for COVID-19

- Laboratories should rely on viral tests to diagnose the presence of SARS-CoV-2 infections

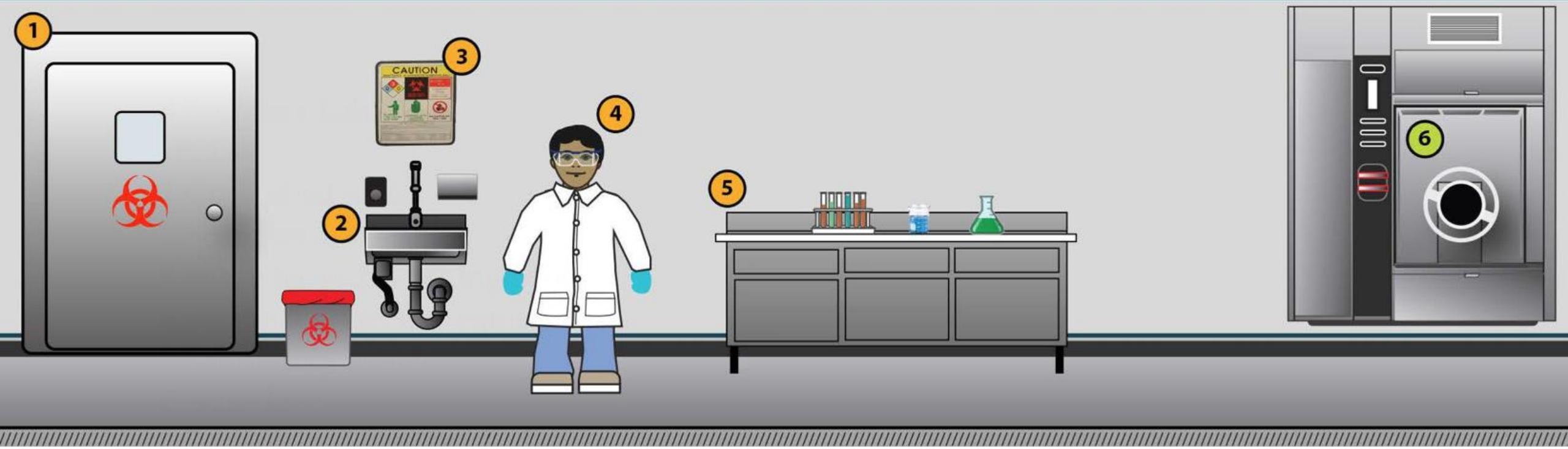
Clinical Laboratory Improvement Amendments (CLIA) certificate

Before conducting SARS-CoV-2 viral testing, a laboratory must be CLIA-certified and meet applicable regulatory requirements

Recommended biosafety level for handling SARS-CoV-2 specimens

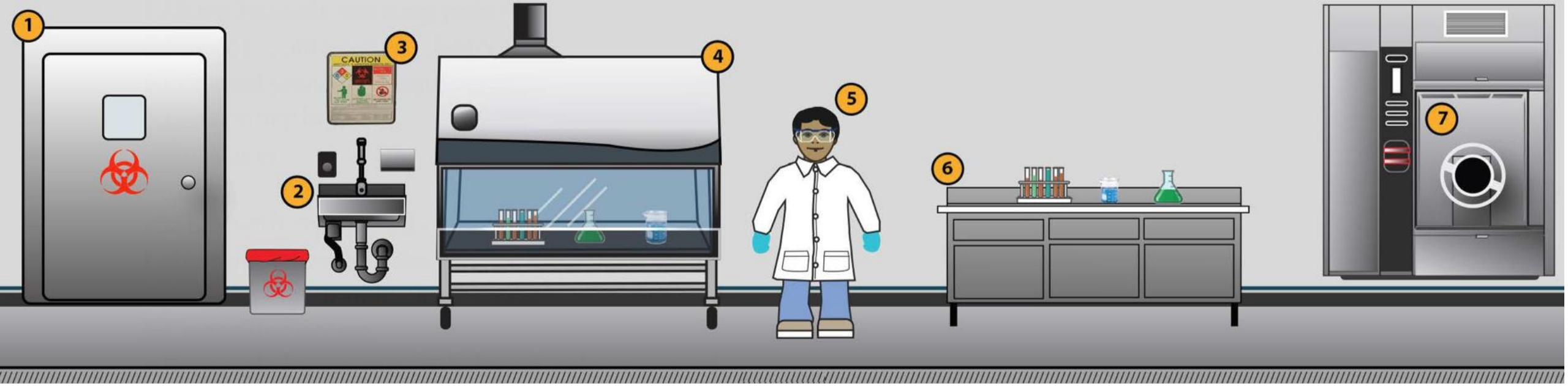


- Routine viral testing of patient specimens, can be handled in a biosafety level 2 (BSL-2) laboratory using standard precautions



Biosafety level 1 (BSL-1) laboratory

Controlled access
Sink
Laboratory bench
Personal protective equipment
Autoclave

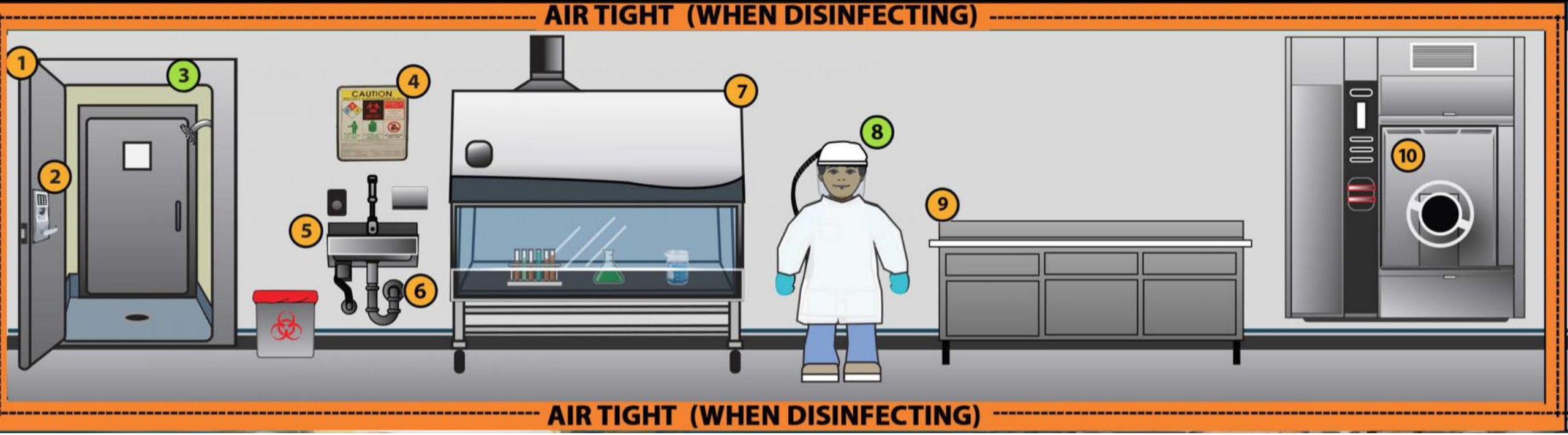


Biosafety level 2 (BSL-2) Laboratory

Controlled access
Sink
Personal protective equipment
Laboratory bench
Autoclave

+

Physical containment device

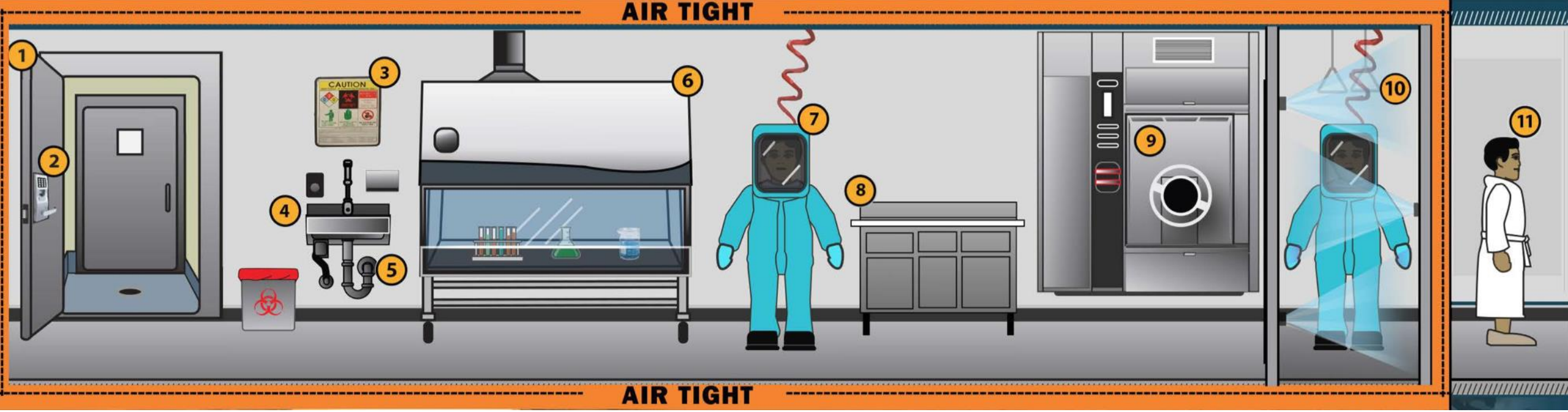


Biosafety level 3 (BSL-3) laboratory

Controlled access
Sink
Personal protective equipment
Laboratory bench
Autoclave

+

Self-closing double door
Personal shower out
Powered air purifying respirator
Exhaust HEPA filter
Sealed penetrations
Effluent decontamination system



Biosafety level 4 (BSL-4) laboratory

Controlled access
Sink
Personal protective equipment
Laboratory bench
Autoclave

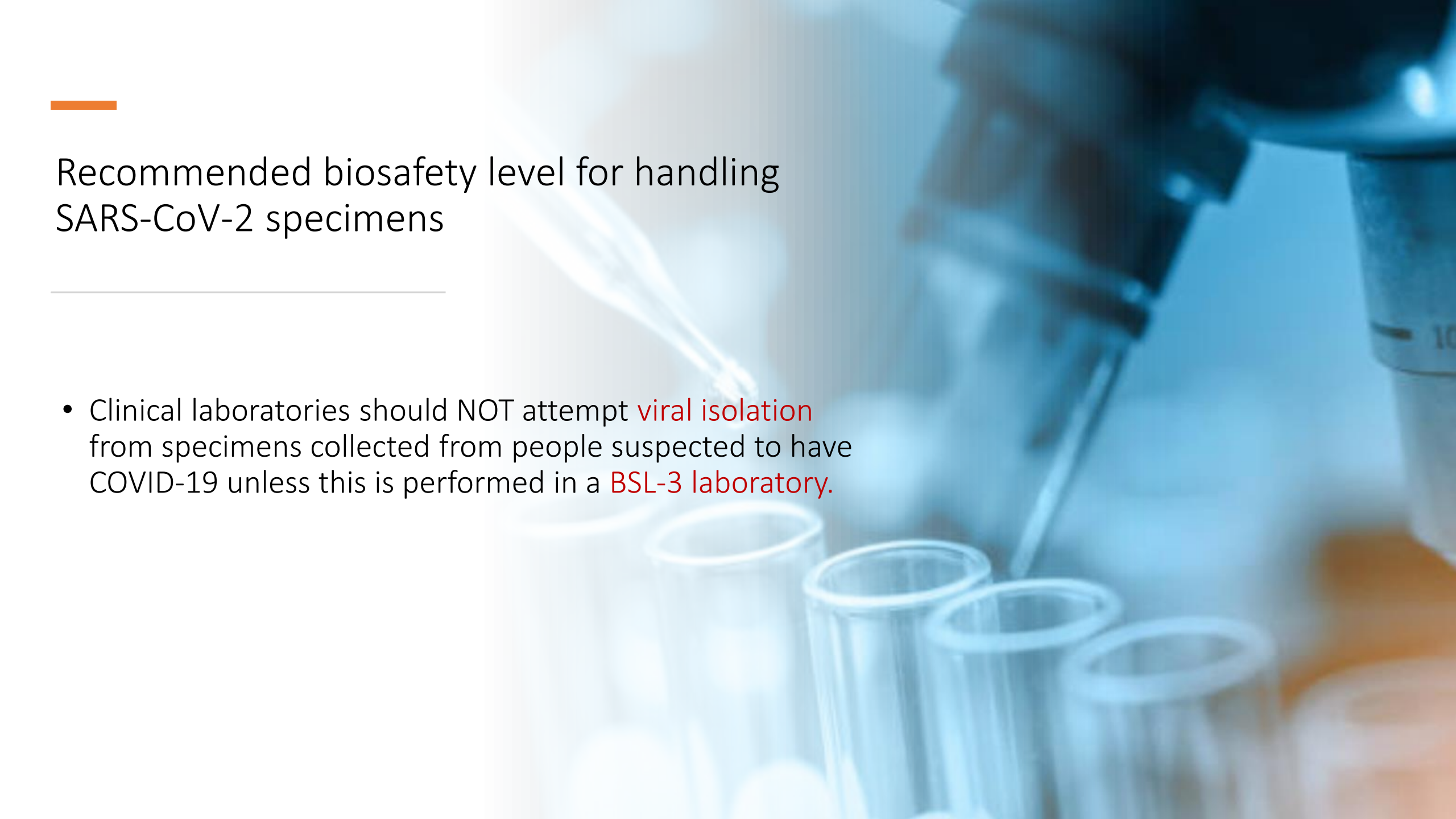
Self-closing double door
Personal shower out
Powered air purifying respirator
Exhaust HEPA filter
Sealed penetrations
Effluent decontamination system

+

Chemical shower out
Positive pressure suit

Recommended biosafety level for handling SARS-CoV-2 specimens

- Clinical laboratories should NOT attempt viral isolation from specimens collected from people suspected to have COVID-19 unless this is performed in a BSL-3 laboratory.



Anatomy of the human respiratory system

Upper respiratory tract

Nasal cavity

Pharynx

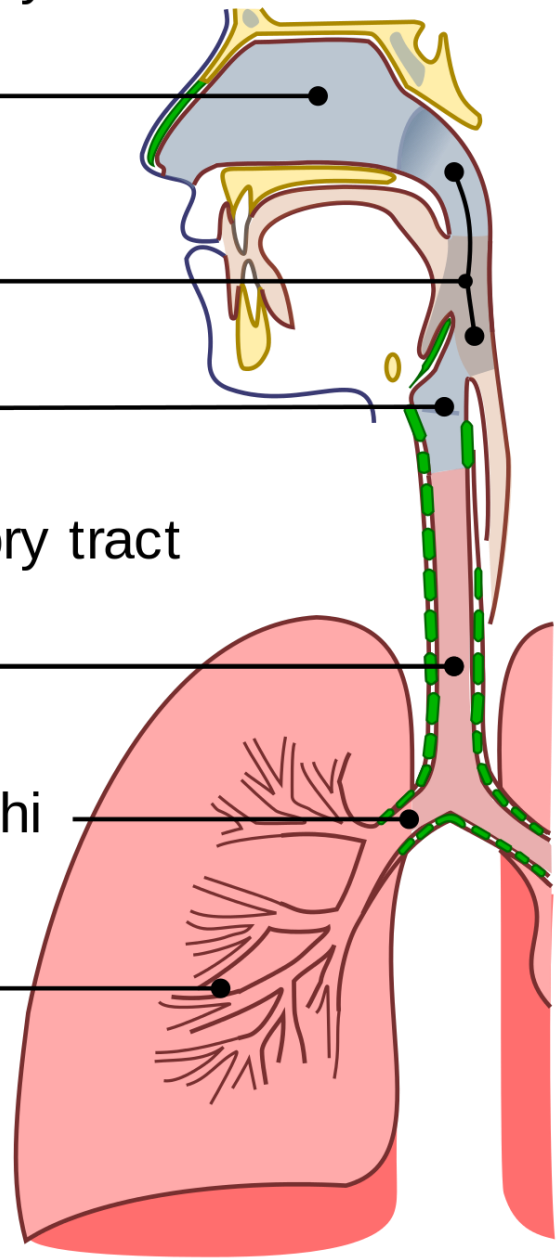
Larynx

Lower respiratory tract

Trachea

Primary bronchi

Lungs

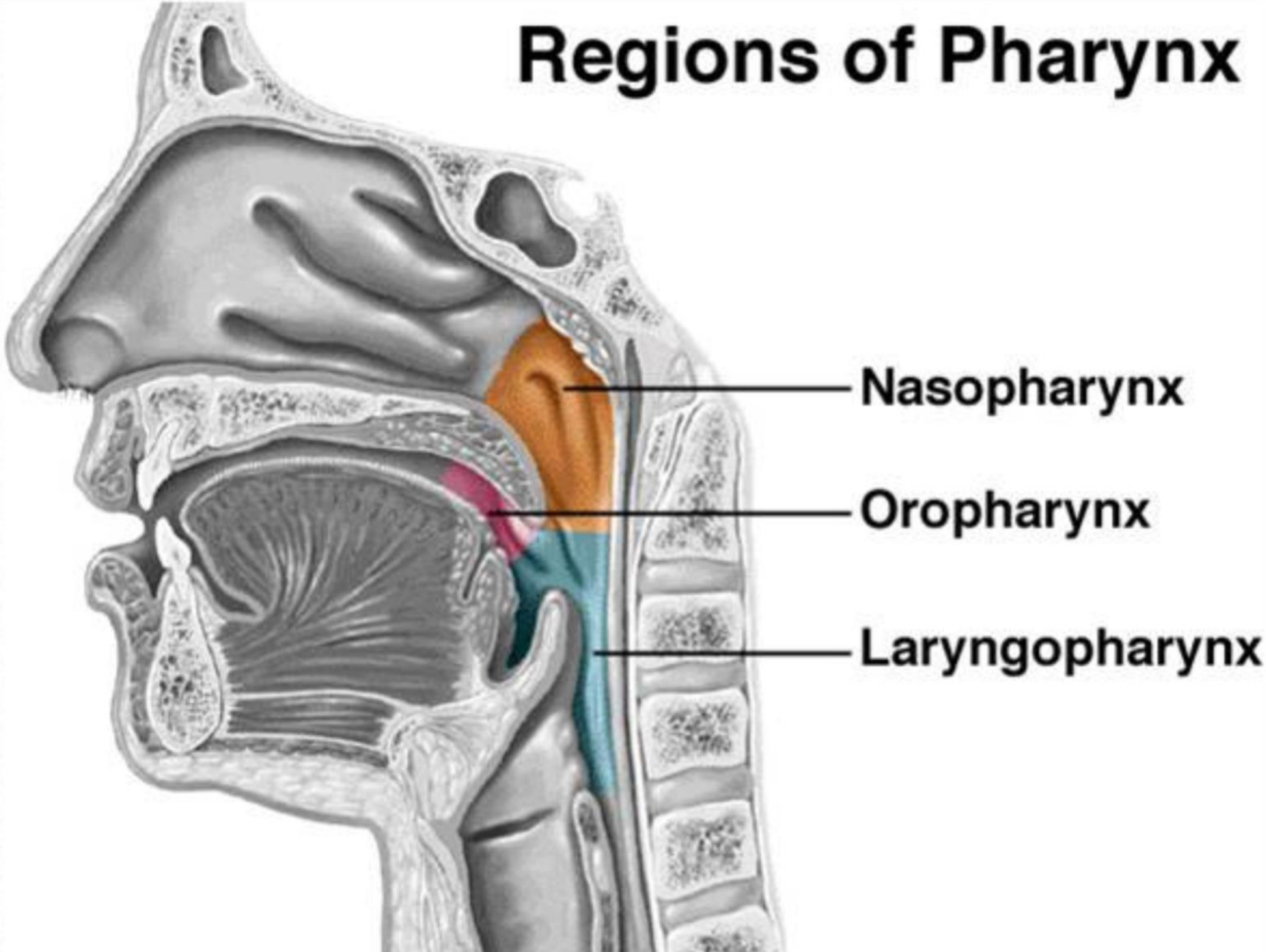


Upper respiratory tract specimens

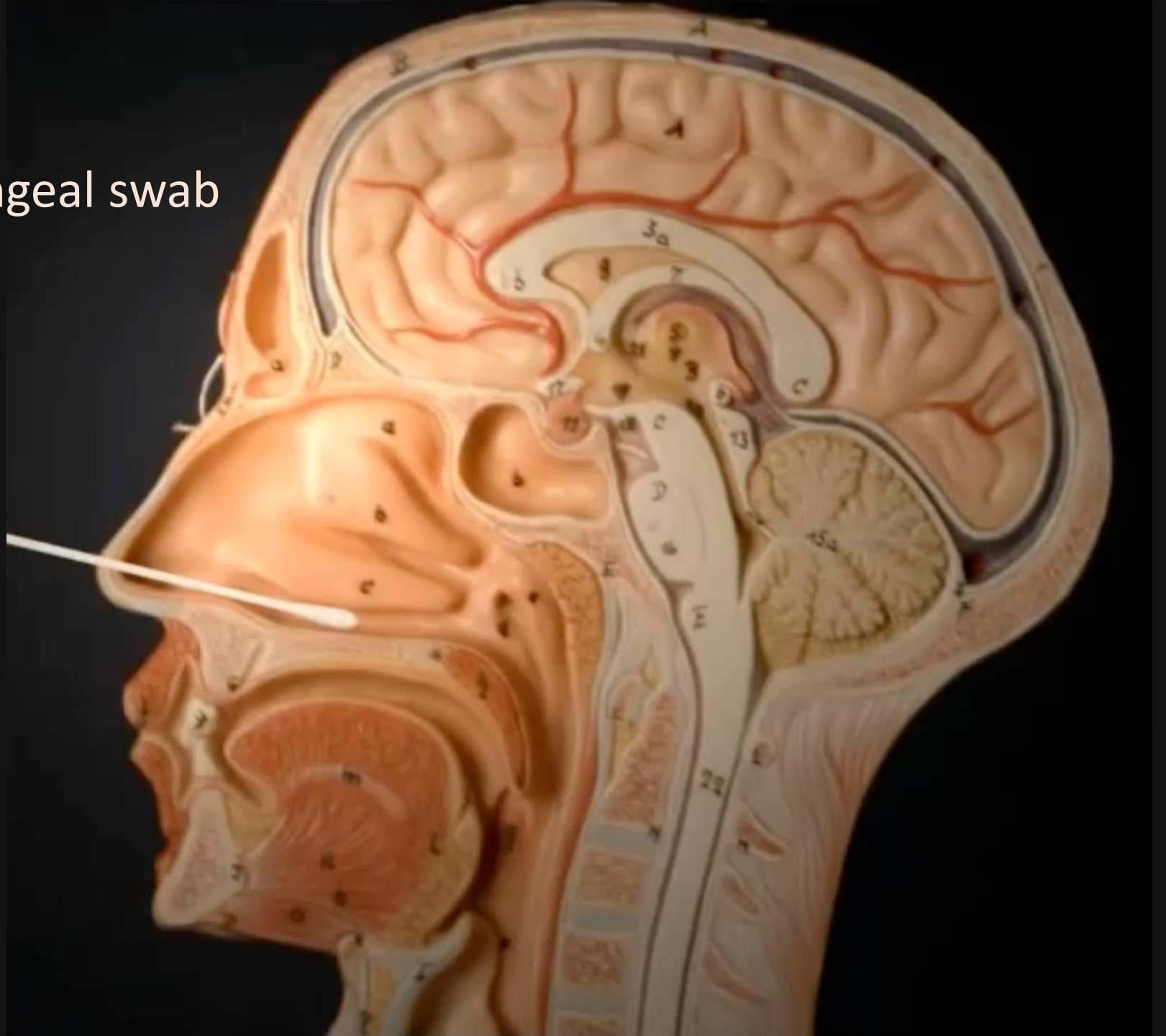
Specimen type

- Oropharyngeal (OP)
- Nasopharyngeal (NP)
- Nasal mid-turbinate (NMT) swab (deep nasal swab)
- Anterior nares (nasal swab)
- Nasopharyngeal wash/aspirate or nasal wash/aspirate (NW)
- Lower respiratory tract aspirate or bronchoalveolar lavage

Regions of Pharynx



Nasopharyngeal swab



Nasopharyngeal/oropharyngeal (NP/OP) swab

- Use only synthetic fiber swabs with plastic or wire shafts
- Do not use calcium alginate swabs or swabs with wooden shafts – they may contain substances that inactivate some viruses and inhibit PCR testing
- CDC is rec'd only the NP swab, although OP swabs remain acceptable
- If both NP and OP swabs are collected, they should be combined in a single tube to maximize test sensitivity and limit use of testing resources.

Nasopharyngeal swab

Nasopharyngeal swab - procedure

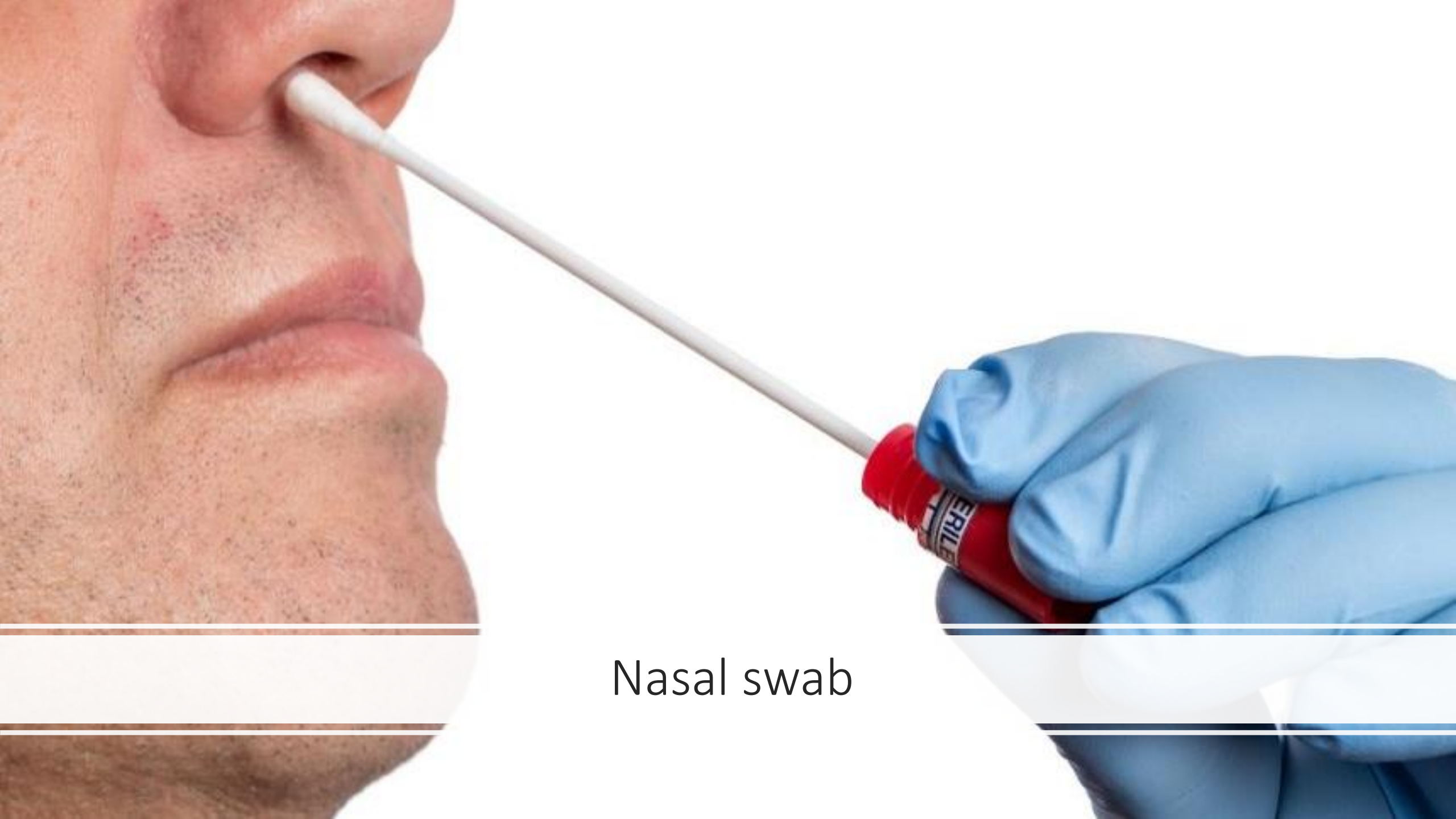
- Insert swab through the nostril parallel to the palate (not upwards)
- Swab should reach depth equal to distance from nostrils to outer opening of the ear
- Gently rub and roll the swab
- Leave swab in place for several seconds to absorb secretions
- Slowly remove swab while rotating it
- Specimens can be collected from both sides using the same swab, but it is not necessary if the minitip is saturated with fluid from the first collection

A nasal mid-turbinate swab

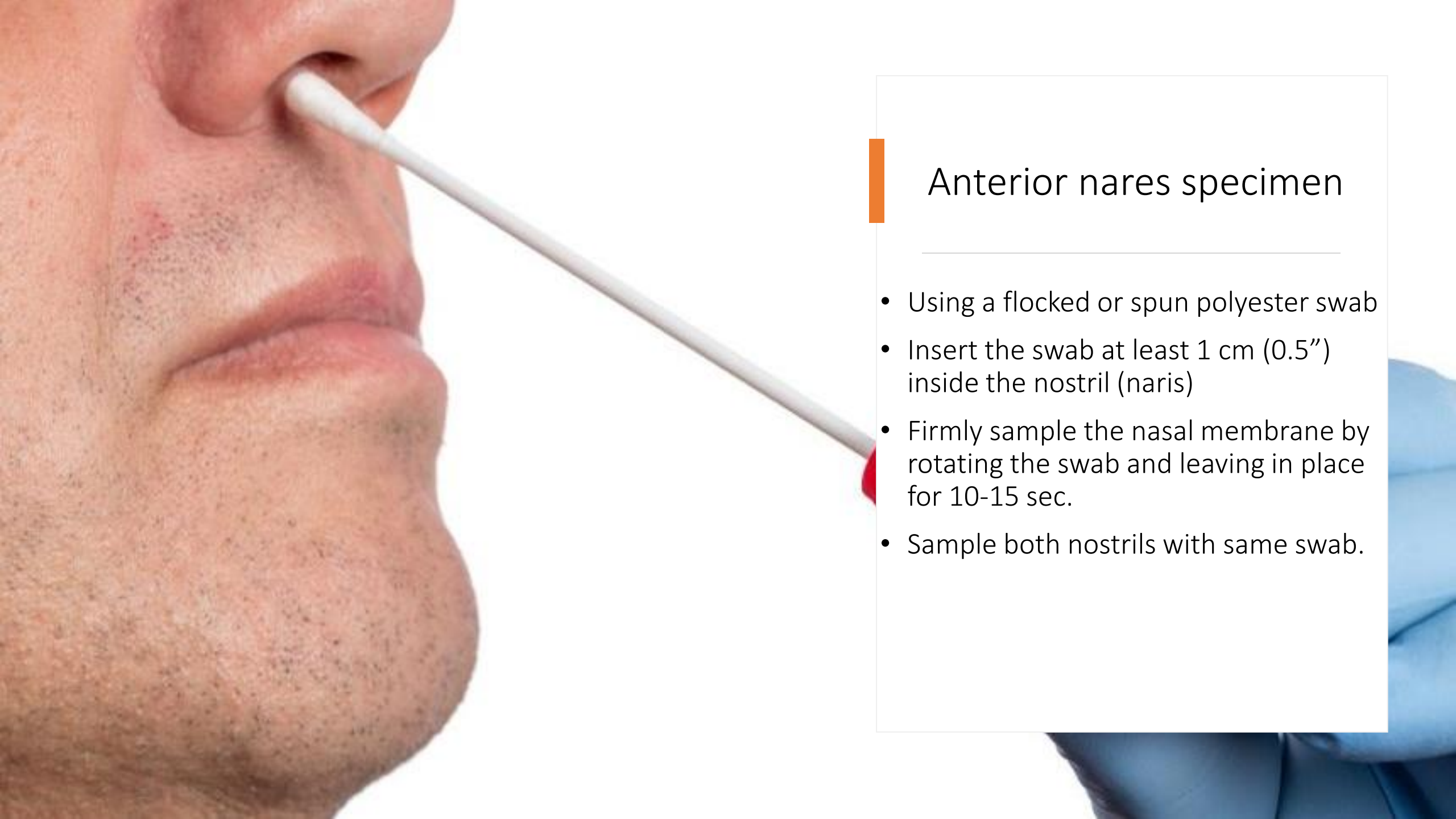
Nasal mid-turbinate (NMT) swab (Deep Nasal Swab)

- Use a flocked tapered swab
- Tilt patient's head back 70º
- While gently rotating the swab, insert swab <1" (2 cm) into nostril until resistance is met
- Rotate the swab several times against nasal wall and repeat in other nostril using the same swab

Flocked tapered swab



Nasal swab



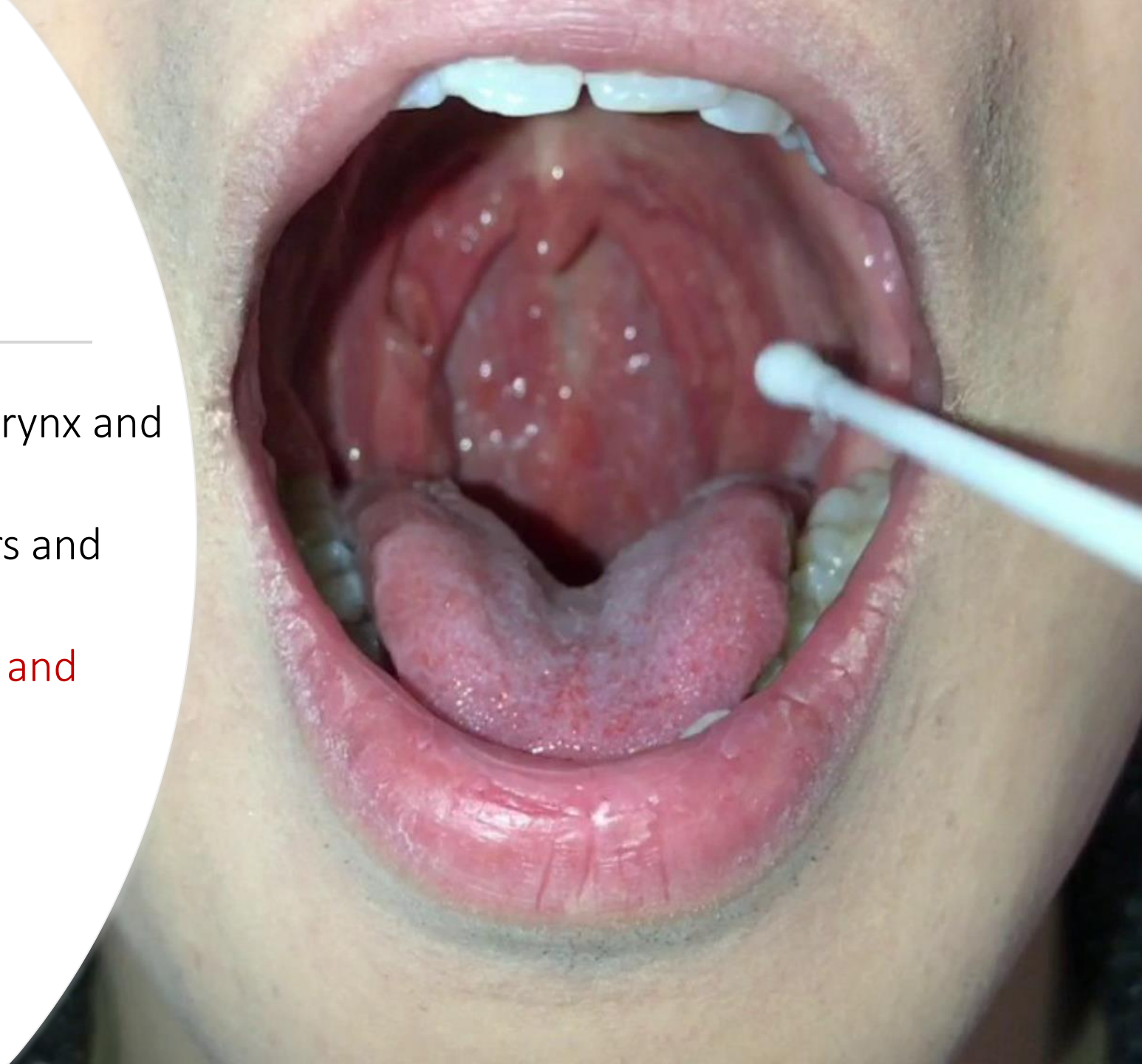
Anterior nares specimen

- Using a flocked or spun polyester swab
- Insert the swab at least 1 cm (0.5”) inside the nostril (naris)
- Firmly sample the nasal membrane by rotating the swab and leaving in place for 10-15 sec.
- Sample both nostrils with same swab.

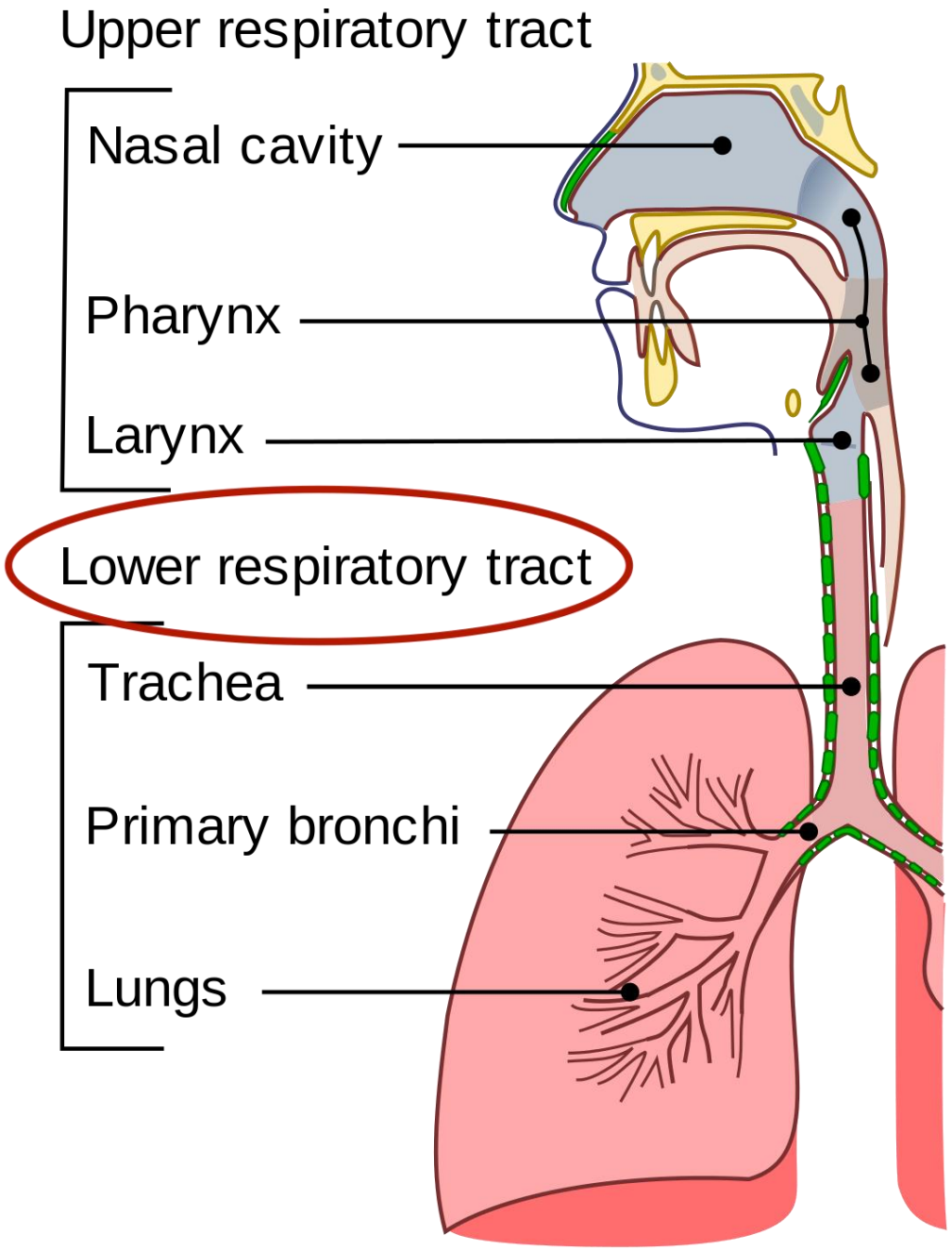
Oropharyngeal swab

Oropharyngeal swab

- Insert swab into the posterior pharynx and tonsillar areas
- Rub swab over both tonsillar pillars and posterior oropharynx
- Avoid touching the tongue, teeth, and gums

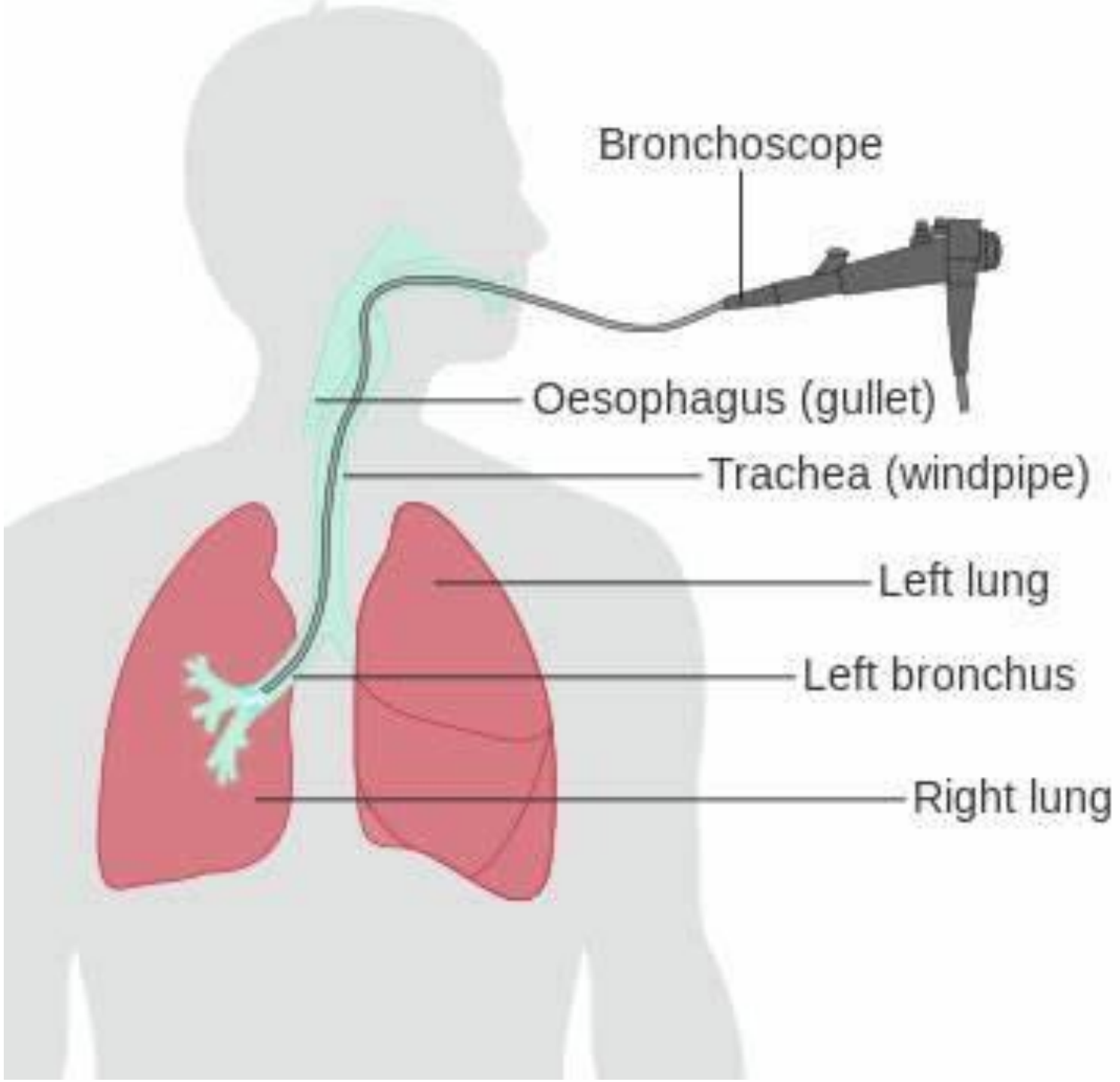


Lower respiratory tract specimens


Upper respiratory tract
Nasal cavity
Pharynx
Larynx
Lower respiratory tract
Trachea
Primary bronchi
Lungs

Bronchoalveolar lavage
(Lower respiratory tract aspirate)

For patients receiving
invasive mechanical ventilation



Specimen handling

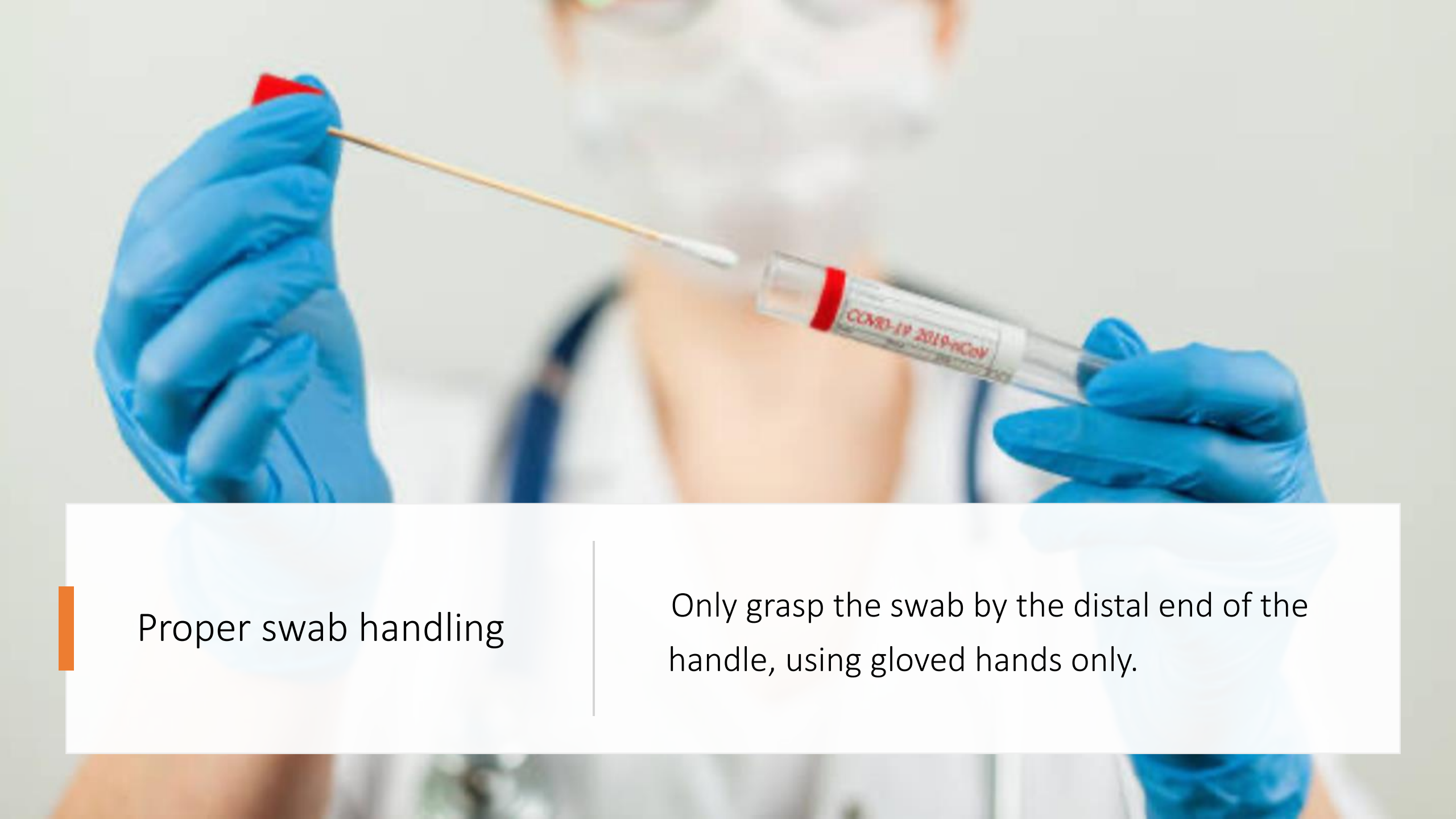
Providers collecting specimens

Use personal protective equipment (PPE) when collecting specimens:

- N95 or higher-level respirator (or facemask if a respirator is not available)
- Eye protection
- Gloves
- Gown

Providers handling specimens but NOT directly involved in collection

- Gloves
- Facemask or cloth face covering



Proper swab handling

Only grasp the swab by the distal end of the handle, using gloved hands only.

Patients self-collecting under clinical supervision

- Hand a swab to the patient while wearing a clean set of gloves.
- The patient can then self-swab and place the swab in transport media
- You can help the patient place the swab into transport media

Specimen handling

- Unless using a test designed to analyze a specimen directly, swabs should be placed immediately into a sterile transport tube containing 2-3 ml of either
  - Viral transport medium (VTM)
  - Amies transport medium
  - Sterile saline

Handling Bulk-Packaged Sterile Swabs

- Individually wrapped (preferred)
- Bulk packaged
  - Avoid SARS-CoV-2 contamination of any of the swabs in the bulk-packaged container

Storage

- Store specimens at 2-8°C (35.6 – 46.4 °F)
- Up to 72 hr after collection
- If a delay in testing or shipping is expected, store specimens at -70°C (-94 °F) or below.

Shipping to CDC

- If repeated testing results remain inconclusive or unusual results are obtained.
- Contact CDC at respvirus@cdc.gov prior to submitting samples
- Ship without delay
- Store specimens at 2-8°C (35.6°F - 46.4°F)
- Ship overnight on ice pack
- If a delay in shipping > 72 hr after collection, store specimens at > -70°C (-94°F), ship overnight to CDC on dry ice

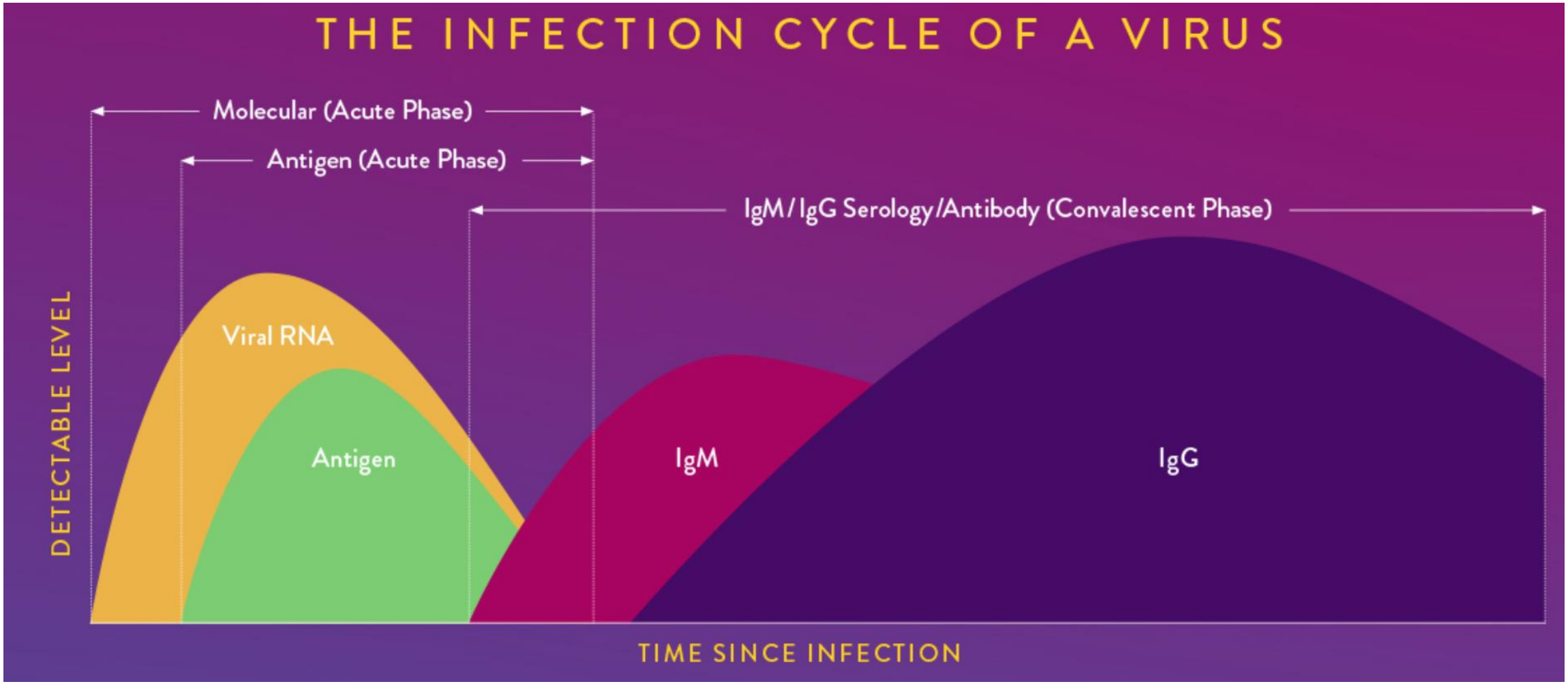
Specimen label should include

- Patient's ID # (e.g., medical record #)
- Unique CDC or state-generated nCov specimen ID (e.g., laboratory requisition #)
- Specimen type (e.g., serum)
- The date the sample was collected
- Complete a CDC Form 50.34 for each specimen submitted.

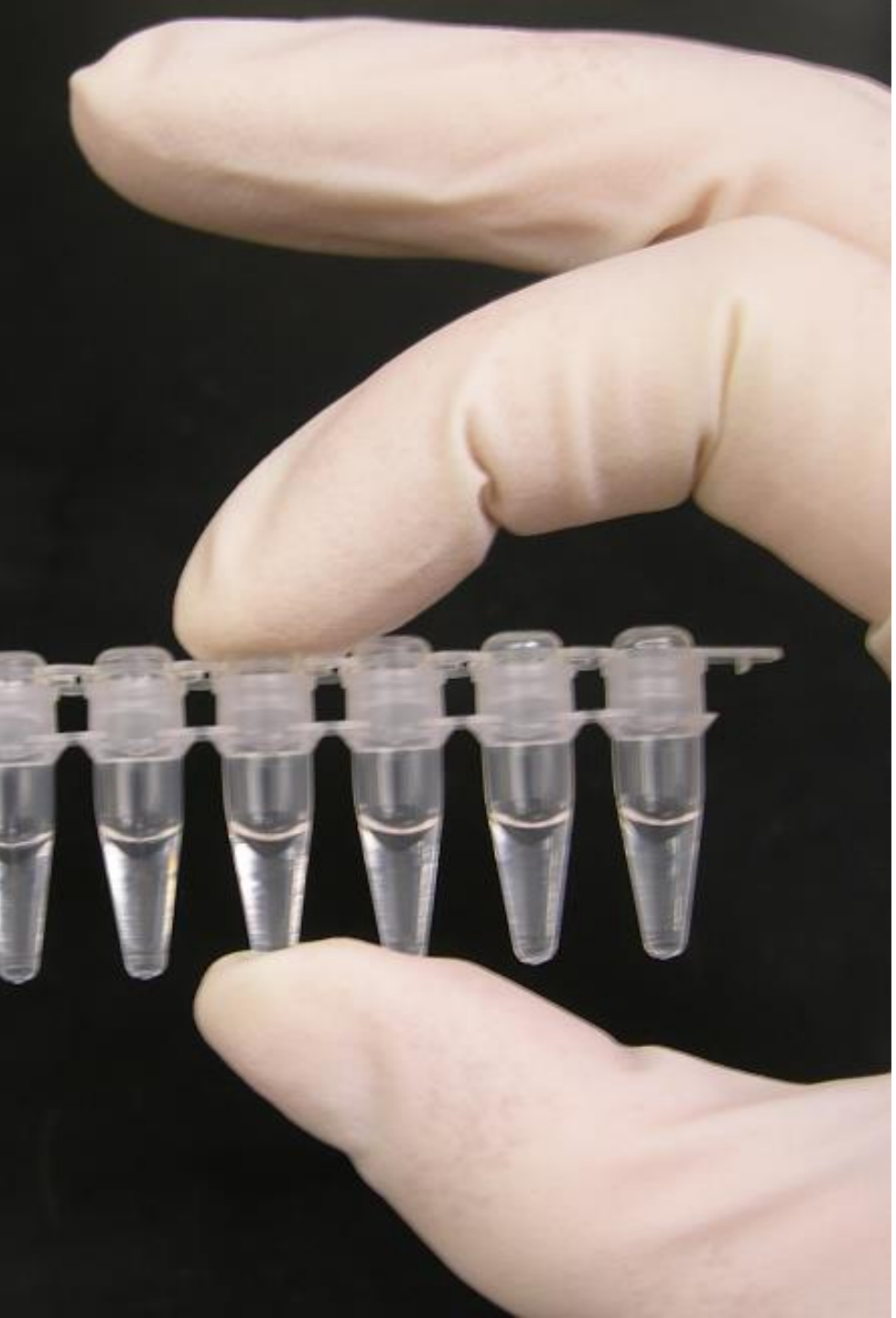
CDC guidance on interpreting COVID-19 test results

Remember…

- No test is ever perfect!
- All tests occasionally yield false positive or false negative results
- Viral test: Performed on swabs using OP, NP or nasal samples. Detects presence of a virus, by testing for virus's RNA or sometimes by testing for the virus's proteins (antigen testing)
- Antibody test (serology): Performed on a blood sample. The results show whether one has been infected with the virus in the past or may be currently infected.


THE INFECTION CYCLE OF A VIRUS
Molecular (Acute Phase)
Antigen (Acute Phase)
IgM/IgG Serology/Antibody (Convalescent Phase)
Viral RNA
Antigen
IgM
IgG
DETECTABLE LEVEL
TIME SINCE INFECTION

Viral testing



Polymerase Chain Reaction (PCR)

- Method used to rapidly make billions of copies of the genetic material of a virus
- When used for SARS-CoV-2, it can identify the presence of the genetic material from the virus

Nucleic Acid (NA) amplification technology

- Abbott ID NOW COVID-19 rapid point-of-care test

- Uses an isothermal nucleic acid amplification technology (detection of nucleic acid from SARS-CoV-2 virus)
- Results in <13 min
- Not FDA cleared or approved. It has been authorized by the FDA under an emergency use authorization (EUA) for use by authorized laboratories and patient care settings

Abbott

Positive viral test result

- Testing for current infection
- Patient most likely has an active COVID-19 infection and can transmit the virus to others
  - “Most likely” since false positive or false negative results can occur

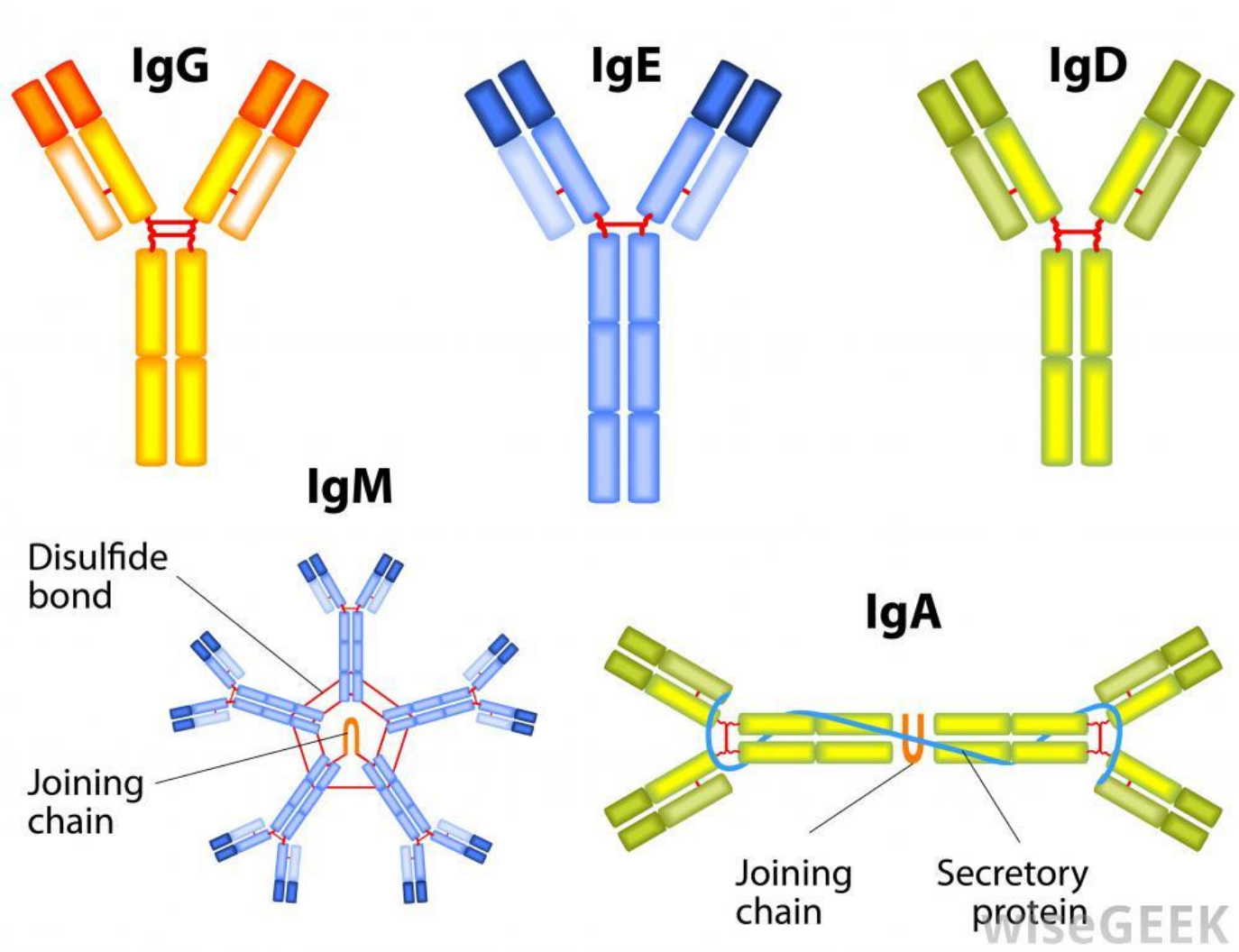
- Rec’d: Stay home and follow CDC guidance

Negative viral test result

- A negative result generally indicates that the patient does not have an active COVID-19 infection
- Patients with symptoms should keep monitoring their symptoms and seek medical advice regarding retesting
- Patients without symptoms should get re-tested only if their medical provider rec'd it
- A negative viral test result does not rule out COVID-19

Antibody testing

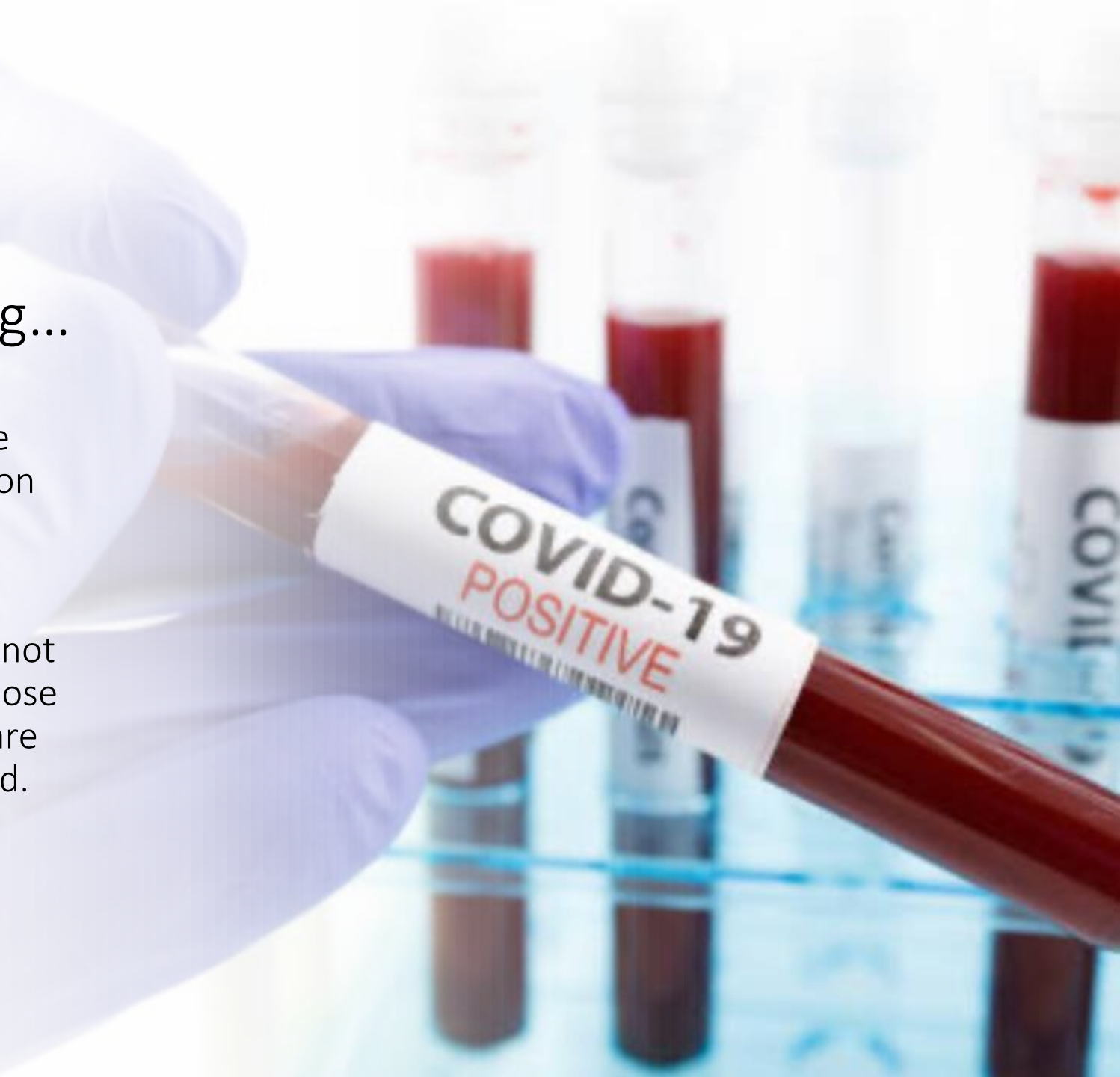
Types of Antibodies

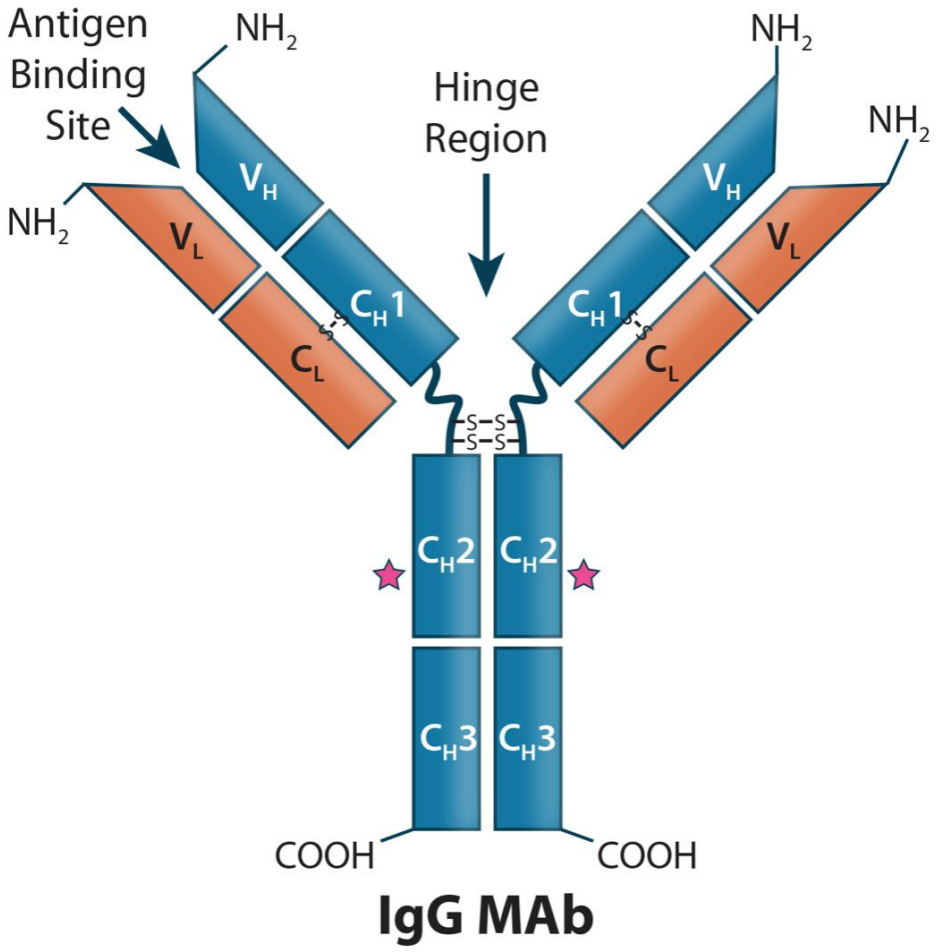


Results from antibody testing…

- Should not be used to diagnose or exclude SARS-CoV-2 infections or to inform infection status.

- Negative results from antibody testing do not rule out SARS-CoV-2 infections, esp. for those who have been exposed to the virus and are still within the estimated incubation period.





Positive antibody test result

- Patient likely has HAD a COVID-19 infection
- Patient may be protected from re-infection (have immunity)

Negative antibody test result

- Patient likely NEVER HAD (or have not yet developed antibodies to) COVID-19 infection
- Patient can still get COVID-19

Both viral and antibody (Ab) test results

Viral test positive

Ab test positive

Patient most likely currently has an active COVID-19 infection

and can transmit the virus to others.

Patient should stay home and follow CDC guidance.

Viral test positive

Ab test negative

Patient most likely currently has an active COVID-19 infection

and can transmit the virus to others

Viral test negative

Ab test positive

Patient likely have had and recovered from a COVID-19 infection.

Patient may be protected from re-infection (have immunity).

Viral test negative

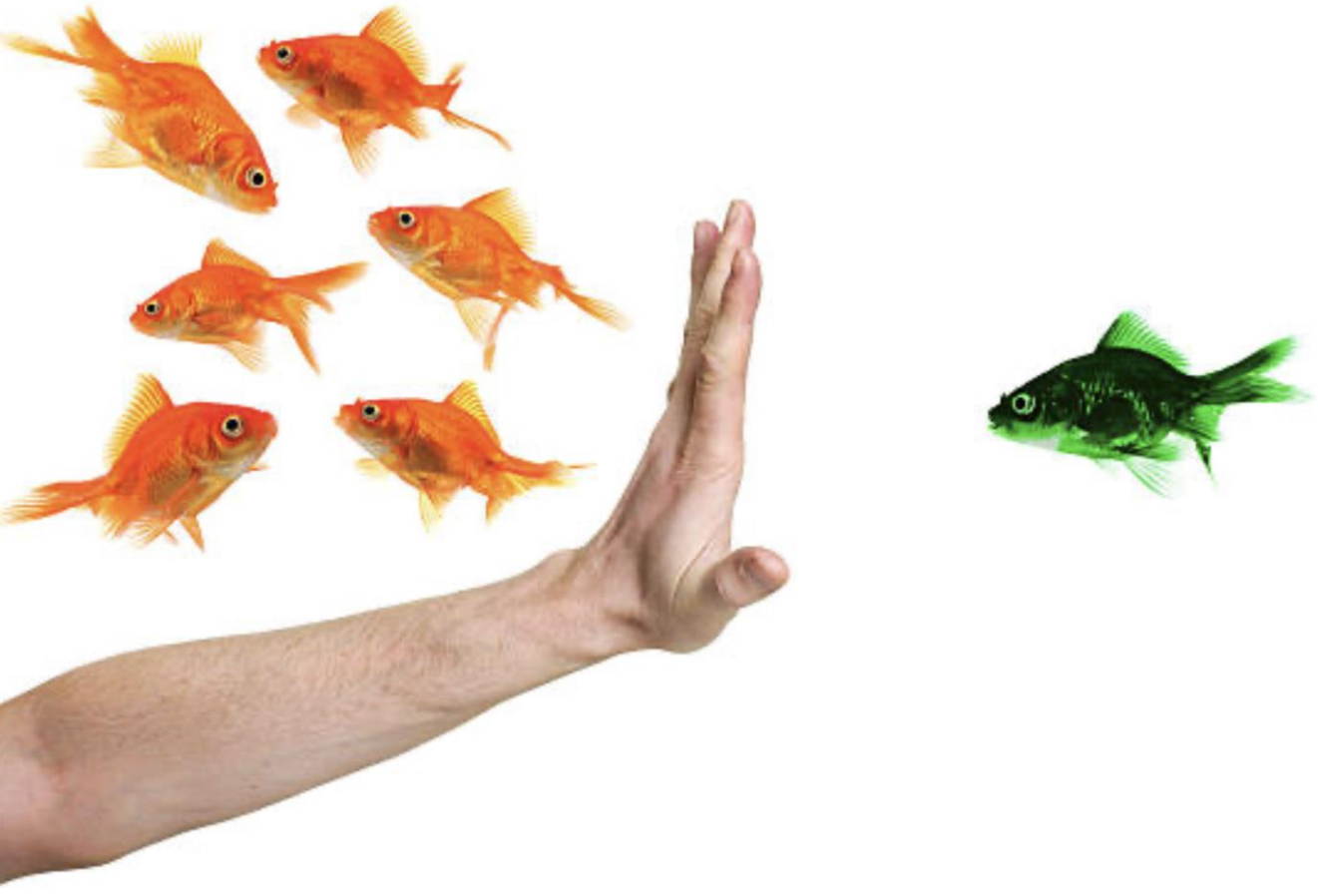
Ab test negative

Patient likely never had a COVID-19 infection.

Patient could still get COVID-19.

Quarantine

Quarantine



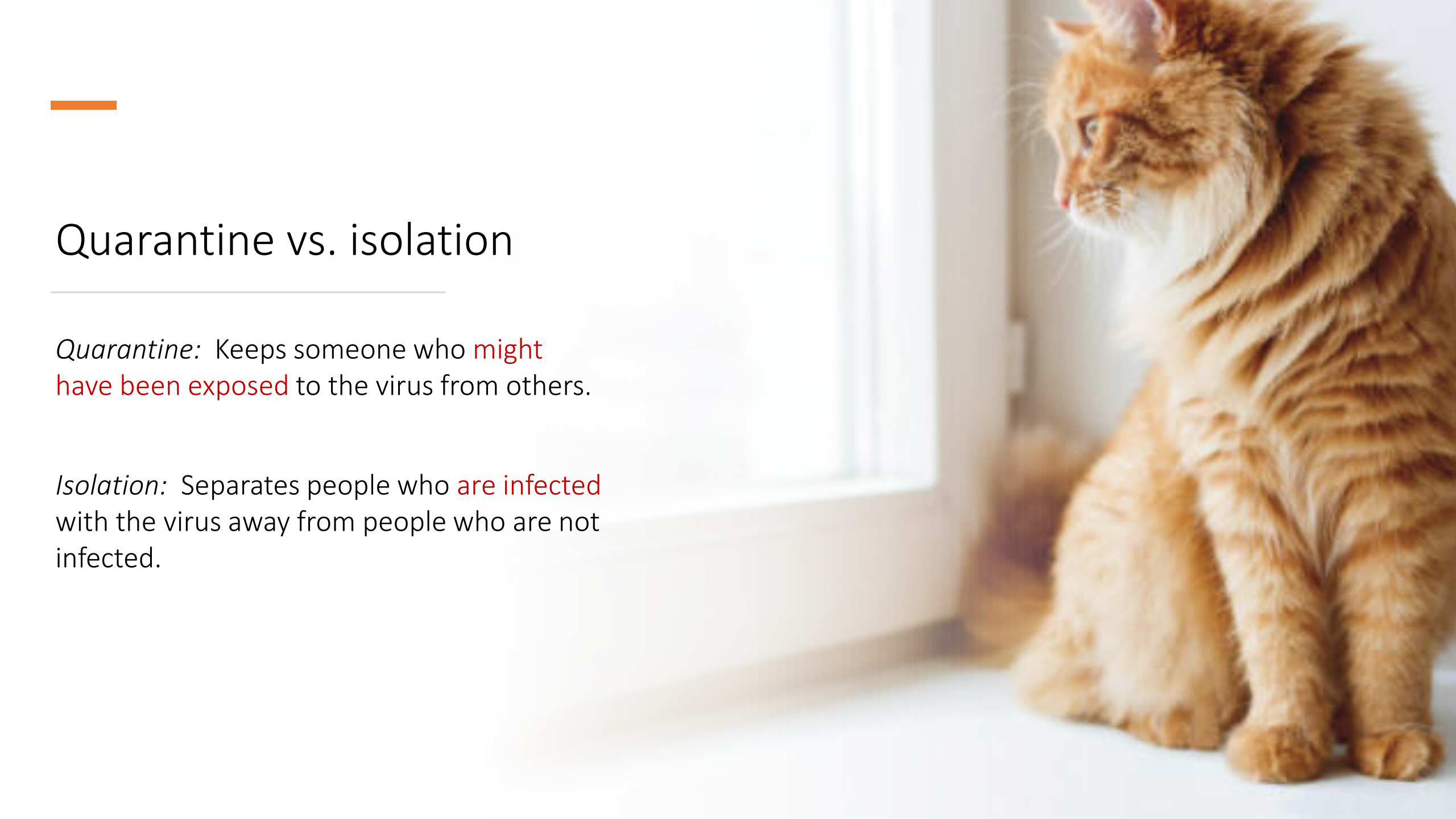
Keep someone who might have been exposed to COVID-19 away from others.

Quarantine helps prevent spread of disease that can occur before a person knows they are sick.

Quarantine vs. isolation

Quarantine: Keeps someone who might have been exposed to the virus from others.

Isolation: Separates people who are infected with the virus away from people who are not infected.



Quarantine rec’d

People in quarantine should

- Stay home
- Separate themselves from others
- Monitor their health
- Follow directions from their healthcare provider

Who needs to quarantine?

Anyone who has been in close contact with someone who has COVID-19

If you've had close contact:

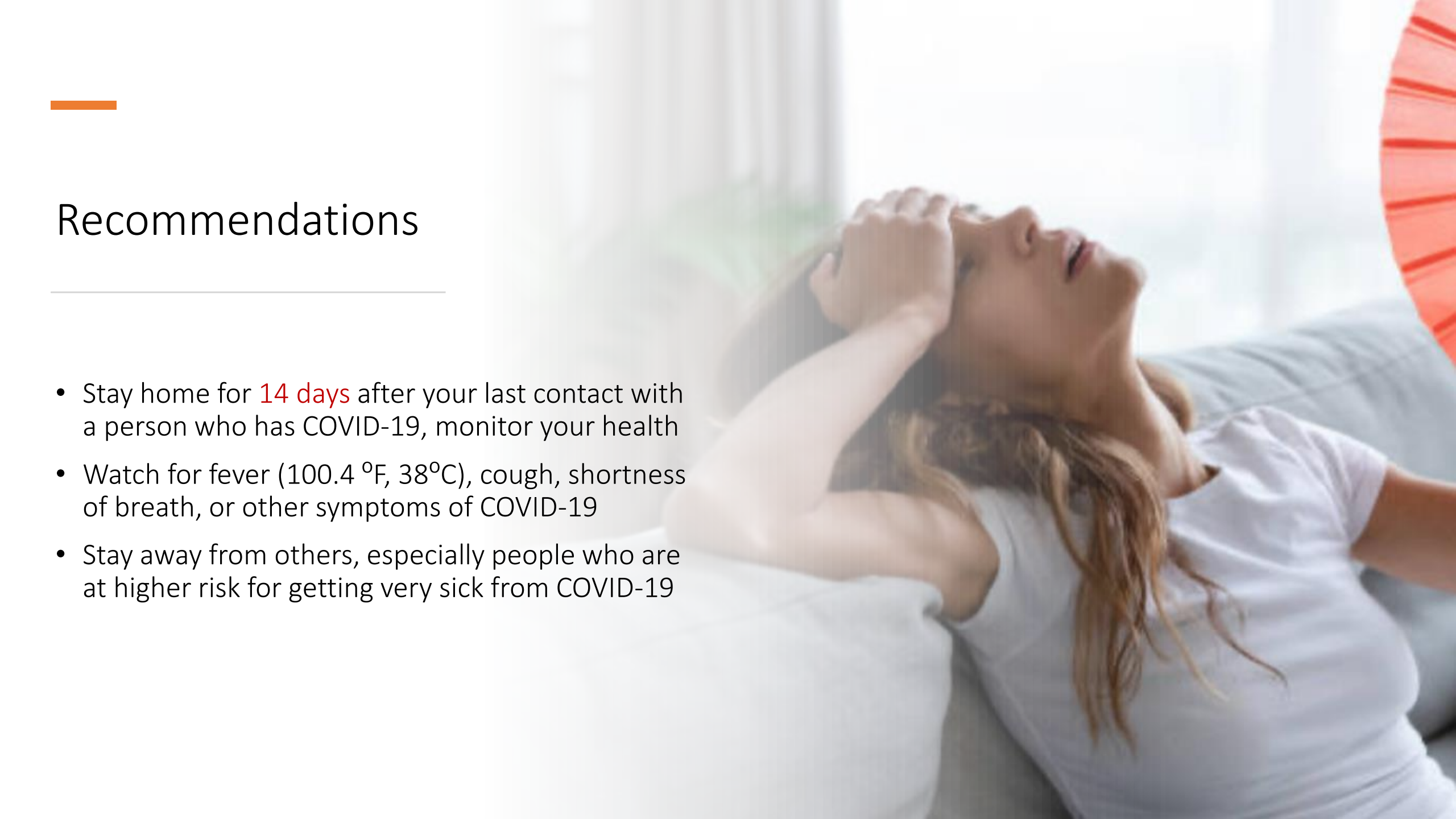
Quarantine even if you previously had COVID-19 or took an antibody test and have antibodies to the virus

What counts as close contact?

- Within 6 ft of someone who has COVID-19 for at least 15 min.
- Direct physical contact with someone who is sick with COVID-19
  - Providing care at home to someone who is sick with COVID-19
  - Sharing eating or drinking utensils
  - Being exposed to respiratory droplets (sneezed, coughed, etc.)

Recommendations

- Stay home for 14 days after your last contact with a person who has COVID-19, monitor your health
- Watch for fever (100.4 ^{o}F, 38^{o}C), cough, shortness of breath, or other symptoms of COVID-19
- Stay away from others, especially people who are at higher risk for getting very sick from COVID-19



Close contact with someone who has COVID-19

- And will not have further close contact
- End of quarantine = date of last close contact with person who has COVID-19 + 14 days

Living with someone who has COVID-19

- Roommate, partner, family member
- That person has isolated by staying in a separate bedroom
- No close contact with the person since they isolated
- End of quarantine = date person with COVID-19 began home isolation + 14 days

Under quarantine + additional contact with COVID-19 confirmed person

- Quarantine starts over!
- Restart your quarantine from the last day you had close contact with anyone who has COVID-19

- End of quarantine = date of additional close contact with person who has COVID-19 + 14 days

Living with someone who has COVID-19 and cannot avoid continued close contact

- Avoid contact with others outside the home while the person is sick
- Quarantine for 14 days after the person who has COVID-19 meets the criteria to end home isolation
- End of quarantine = date the person with COVID-19 ends home isolation + 14 days

Thank you. Any questions?

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