



**PHARMACY
VISION
20/20**

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RESORT

COVID-19 POINT-OF-CARE TESTING

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DISCLOSURE

I have no financial or other disclosures to report.

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- Mention of any specific brand name, product or technique is intended only to cite an example, and is not an endorsement by the presenter.
- The material and information contained in this presentation is intended to be most current at the time of slide submission. Since information on COVID-19 and testing is rapidly developing, audience is recommended to perform their own research for the most up-to-date information regarding this topic.

LEARNING OBJECTIVES FOR PHARMACISTS

- Explain the types of POC test available, the characteristics of these tests, and whom and when patients should be tested
- Describe the process and requirements for applying a CLIA waiver
- Identify areas to consider before implementing COVID-19 POC testing
- Explain the potential roles of pharmacists for providing POC testing

LEARNING OBJECTIVES FOR PHARMACY TECHNICIANS

- Explain the types of POC test available, the characteristics of these tests, and whom and when patients should be tested
- Understand the workflow of processing COVID-19 testing
- Discuss questions commonly asked by patients regarding COVID-19 tests
- Explain the potential roles of pharmacy technicians for providing POC testing



ASSESSMENT QUESTIONS...

ASSESSMENT QUESTION #1

Only COVID-19 tests that received the Emergency Use Authorization under the Public Readiness and Emergency Preparedness Act (PREP) are approved by the FDA.

- A. True
- B. False

ASSESSMENT QUESTION #2

Which of the following is true regarding CLIA waivers?

- A. It is required when a pharmacy collects specimen and send to a lab for testing
- B. A collaborative practice agreement needs to be in placed before CLIA-waived tests can be performed
- C. A separate CLIA waiver is needed for each mobile pharmacy unit
- D. The application form is available at the CMS website or local health department

ASSESSMENT QUESTION #3

Which of the following is considered a good practice when incorporating COVID-19 testing in your workflow? Select the best answer.

- A. Offer as many testing windows as possible to accommodate patients
- B. Change gloves between each patient
- C. Collect cash payment from patients as reimbursement is still in a preliminary stage
- D. Bill testing under Medicare part B as a physician service

GLOSSARY

- Point-of-care test (near-patient testing)
 - Test that takes place at the time of patient care with instant availability of results to make immediate & informed decisions
- Viral test – also referred as “molecular” or “antigen” test
- PCR- Polymerase Chain Reaction- method used for making many copies of a RNA or DNA sample. It may be used for detecting viruses.
- Clinical Laboratory Improvement Amendments (CLIA) waiver
 - Grants authorization to test human specimens for diagnosis, prevention, or treatment of a disease

GENERAL INFORMATION ABOUT SARS-CoV-2

- Corona viruses
 - A group of single-stranded RNA viruses that affect mammals and birds
 - Examples
 - Severe Acute Respiratory Syndrome (SARS)
 - Middle East Respiratory Syndrome (MERS)
- Transmission
 - Person-to-person through respiratory droplets¹
 - By touching a surface that has the virus and then touching nose, mouth or eye

SYMPTOMS OF COVID-19 INFECTION

Develop 2-14 days after exposure ²:

- Fever or chills
- Cough
- Fatigue
- **Muscle or body aches**
- Shortness of breath
- Headache
- Sore throat
- Congestion or runny nose
- Nausea or vomiting, diarrhea
- **New loss of smell or taste**

Emergency warning signs ²:

- Trouble breathing
- Persistent pain or pressure in the chest
- New confusion
- Inability to wake up or stay awake
- Bluish lips or face

WHY TESTING IS SO IMPORTANT

- Quick identification of cases ³
- Prompt treatment & isolation of those who are infected
- Identify anyone who came into contact with infected patient (or their family) so they can be quickly treated

TYPES OF COVID-19 TESTS

Molecular test

Molecular tests detect genetic material from the virus.



Antibody test

These tests detect antibodies: Y-shaped molecules made by the immune response to disable a virus or mark it for destruction.

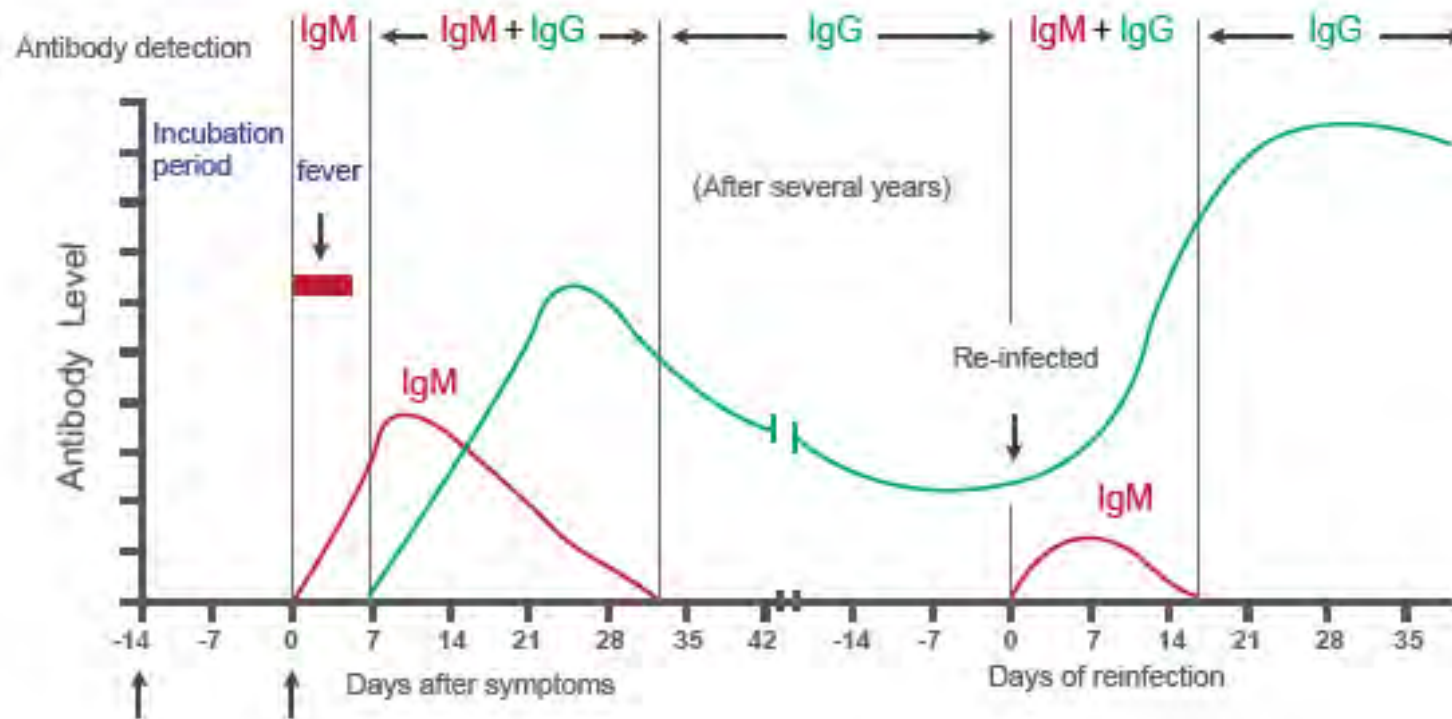


Antigen test

This is the newest of the three testing types. These tests detect antigens: pieces of a virus that the immune system recognizes. A single virus has many antigens.



ANTIBODY RESPONSE TO COVID-19



	Molecular test	Antibody test	Antigen test
Sample Collection	Collects infected cells via nasal or throat swab	Collects antibodies produced by B cells via blood	Collects infected cells via nasal swab
What it detects	Current infection	Past infection	Current infection
Advantage	Identifies those infected so treatment can be initiated and potential contacts can be traced	Identifies those who may have immunity	Provides same info as molecular test in 15 minutes
Limitation	Negative result doesn't guarantee immunity	Immunity longevity, level, and kind of antibody response are unknown	Negative result does not guarantee immunity. Not as accurate as molecular test

HOW IS TEST PERFORMANCE MEASURED?

When there is no gold-standard test, performance is indexed by:

- **Positive percent agreement** - proportion of true positives in the total positive results (true positives and false negatives)
- **Negative percent agreement** - proportion of true negatives in the total negative results (true negatives and false positives)
- **Sensitivity** and **specificity** are reported by some manufacturers that used PCR to validate their POC test results
- A test that has high negative and/or positive percent agreement is considered highly accurate

HOW ACCURATE ARE THESE TESTS?

Results depend on various factors:

- Patient-specific factors
- Test being used
- What a test is measuring
- Interpretation of test results

When there is no gold-standard test:

- Positive and negative percent agreement
- PCR test vs serology test

WHAT WE CURRENTLY KNOW ABOUT ACCURACY

Molecular Testing

- Reported Rate of False Negative: **2-37%**
- Highly Specific- Close to zero false positives
- Tests using deep nasal swabs have less false negatives than saliva or throat swabs

Antibody Testing

- The range of false negatives: 0-30%⁶
- Tests conducted (<7 days post symptoms) can result in false negative

Antigen(Rapid) Testing

- Reported Rate of False Negative: may be as high as **50%**
- Experts recommend to repeat rapid testing
- Highly Specific near **Zero** False Positives
- Newer tests have improved accuracy

CATEGORIES FOR SARS-CoV-2 TESTING

CDC recommends testing with viral tests (nucleic acid or antigen) for:

- Individuals with signs or symptoms consistent with COVID-19
- **Asymptomatic individuals with recent known or ~~suspected~~ exposure (within 6 feet \geq 15mins) to confirmed SARS-CoV-2, to control transmission**
- Asymptomatic individuals in a high SARS CoV-2 transmission zone who attended a gathering of more than 10 people without mask or distancing.
- Individuals being tested to determine resolution of infection(**ONLY** for severely immunocompromised patients in consultation with infectious disease experts.)
- Some individuals may need testing if they: live or work in a nursing home, are a first responder, critical infrastructure worker, healthcare provider, or a patient being admitted to a hospital. ⁷

HOW ABOUT UNIVERSAL TESTING?

Smart testing ⁸:

- Most likely to have the disease (e.g. individuals with symptoms or identified by contact tracing).
- Suffer greatly if they were to have the disease (e.g. the elderly and those with underlying conditions)
- Repetitive contacts in close quarters and cannot always practice physical distancing (such as first responders, mass transit workers, grocery store employees, and health care workers)
- In confined group living situations (senior living facilities, prisons, etc.)
- Hospitalized or having procedures, in order to protect patients and health care workers

RECOMMENDATIONS FOR ANTIBODY TESTING

As of Sept 18, 2020, CDC does not recommend using antibody testing as the sole basis for diagnosis of acute infection, and antibody tests are not authorized by FDA for such diagnostic purposes

- *In certain situations, serologic assays may be used to support clinical assessment of persons who present late in their illnesses when used in conjunction with viral detection tests.*
- Serologic assays for SARS-CoV-2, now broadly available, can play an important role in understanding the transmission dynamic of the virus in the general population and identifying groups at higher risk for infection

PUBLIC READINESS AND EMERGENCY PREPAREDNESS

U.S. Department of Health & Human Services
Office of the Assistant Secretary for Health
Wednesday, April 8, 2020

Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act

On January 31, 2020, the Secretary of Health and Human Services declared that the 2019 novel coronavirus (COVID-19) is a public-health emergency for the United States. The United States Department of Health and Human Services (HHS) is the lead agency for the federal government's response to the COVID-19 pandemic.

A key component of that response is rapidly expanding COVID-19 testing across America. Within HHS, the Office of the Assistant Secretary for Health leads federal efforts to support that expansion.

Pharmacists, in partnership with other healthcare providers, are well positioned to aid COVID-19 testing expansion. Pharmacists are trusted healthcare professionals with established relationships with their patients. The vast majority of Americans live close to a retail or independent community-based pharmacy. That proximity reduces travel to testing locations, which is an important mitigation measure. Pharmacists also have strong relationships with medical providers and hospitals to appropriately refer patients when necessary.

Therefore, as an Authority Having Jurisdiction under the Secretary's March 10, 2020 declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), OASH issues this guidance authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized. *See* 85 Fed. Reg. 15,198, 15,202 (March 17, 2020); *see also* Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e.¹ By doing so, such pharmacists will qualify as "covered persons" under the PREP Act. And they may receive immunity under the PREP Act with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of FDA-authorized COVID-19 tests. 42 U.S.C. § 247d-6d(a)(1).

Department of Health & Human Services - April 8, 2020:

Public Health Emergency

- Authorized licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the FDA has authorized⁹

<https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf>

CALIFORNIA STATE LAW



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Order Extending May 12, 2020, Order Waiving Restrictions on Pharmacists Ordering and Collecting Specimens for COVID-19 Tests By 60 Days

On March 4, 2020, the Governor proclaimed a [State of Emergency](#) to exist in California as a result of the impacts of COVID-19 to make additional resources available, formalize emergency actions already underway across multiple state agencies and departments, and help the state prepare to respond to an increasing number of individuals requiring medical care and hospitalization as a result of a broader spread of COVID-19.

Pursuant to the Governor's Executive Order [N-39-20](#), during the State of Emergency, the Director of the California Department of Consumer Affairs may waive any statutory or regulatory professional licensing requirements and amend scopes of practice pertaining to individuals licensed pursuant to Division 2 of the Business and Professions Code.

On May 12, 2020, the Director issued an Order Waiving Restrictions on Pharmacists Ordering and Collecting Specimens for COVID-19 Tests. The order is scheduled to expire on July 11, 2020.

The Director hereby extends the Order Waiving Restrictions on Pharmacists Ordering and Collecting Specimens for COVID-19 Tests by an additional 60 days. The order now terminates September 9, 2020, unless further extended.

This order is effective immediately and may be amended from time to time in the discretion of the Director.

Dated: July 7, 2020

Signature on File

Kimberly Kirchmeyer
Director

CA Department of Consumer Affairs

State of Emergency – May 12, 2020:

- Authorized licensed pharmacists to order and collect specimens for COVID-19 tests
- The pharmacist is competent & trained to collect the specimen under the provisions of EUA
- These tests are considered as “medical device”
- https://www.dca.ca.gov/licensees/pharmacists_covid19_tests.pdf

CALIFORNIA STATE LAW (CONTINUE)

Governor of California Signs Executive Order Permitting Pharmacists, Pharmacy Technicians to Conduct CLIA-waived COVID-19 Tests

2020-08-26 18:45:00

Alana Hippensteele, Editor

California Governor Gavin Newsom issued an executive order in his state to increase the availability of Clinical Laboratory Improvement Amendments (CLIA)-waived coronavirus disease 2019 (COVID-19) testing. The order also addresses other issues related to the state's needs during the COVID-19 pandemic.^{1,2}

Aug 26, 2020:

Allows Pharmacists and Pharmacy technicians to conduct CLIA end to end COVID-19 tests.

COVID-19 testing kits need to have EUA status.

EMERGENCY USE AUTHORIZATION

EUA or approval?

- Are they the same?

No, Emergency Use Authorization (EUA) and full approval are not the same

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

- Full FDA approval is very rigorous

COVID-19 TEST WITH EMERGENCY USE AUTHORIZATION

Coronavirus Disease 2019 (COVID-19) EUA Information

- [Coronavirus Disease \(COVID-19\) updates from FDA](#)
- **Overviews:**
 - [FDA Combating COVID-19 With Medical Devices](#) (PDF, 708 KB)
 - [FDA Combating COVID-19 With Therapeutics](#) (PDF, 610 KB)
 - [EUA Authorized Serology Test Performance](#)
- **Detailed Information for all COVID-19 EUAs, including authorizations and fact sheets**
 - [In Vitro Diagnostic Products](#)
 - [High Complexity Molecular-Based Laboratory Developed Tests](#)
 - [SARS-CoV-2 Antibody Tests](#)
 - [Personal Protective Equipment and Related Devices](#)
 - [Ventilators and Other Medical Devices](#)
 - [Drug Products](#)

The website lists all products with current EUAs

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

- Need to scroll down to find the sections for molecular & antibody tests

APPLYING FOR A CLIA-WAIVER



Free POC COVID-19 Tests
Facilities With No CLIA
Waiver will Miss Out

WHO NEEDS A CLIA WAIVER?

Anyone who performs testing of human specimens for the diagnosis, prevention or treatment of disease or health problems must apply for a CLIA certificate. This includes physicians who operate their own in-office laboratories

- *Waived tests include test systems cleared by the FDA for home use and those tests approved for waiver under the CLIA criteria*¹³
- Waived tests must be simple and have a low risk for erroneous results
- If your pharmacy only collects specimens to be sent out for testing at another facility, then CLIA certification is not required

CLIA-WAIVED STATUS FOR POINT-OF-CARE SARS-CoV-2 TESTS UNDER EMERGENCY USE AUTHORIZATIONS

On April 9, 2020, FDA clarified that:

- When it grants an Emergency Use Authorization (EUA) for a point-of-care test, that test is deemed to be CLIA-waived
- For the duration of the national emergency declaration for COVID-19, such tests can be performed in any patient care setting that operates under a CLIA Certificate of Waiver
- Tests that are offered prior to or without an EUA have not been reviewed by FDA, are not FDA authorized, and have not received a CLIA categorization. Thus, those tests are considered high complexity by default until they receive an EUA or other FDA approval that indicates they may be performed as moderate complexity or waived test

HOW DO I APPLY FOR A CERTIFICATE OF WAIVER?

To qualify for a CLIA waiver, the pharmacy must only perform tests that have received the CLIA waived status

- Fill out application form CMS-116 at the CMS website (www.cms.gov/clia) or from local health department
- Send completed form to CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
- Once state processed, the pharmacy will receive an invoice from CMS in Maryland (In around 4-6 weeks)¹⁶
- Need a CLIA certificate for each pharmacy location except
 - When testing location changes, such as mobile units
 - If performing limited testing, i.e. not-for-profit, state or local government
 - When testing within a hospital and are located at contiguous buildings on the same campus

AREAS TO CONSIDER BEFORE YOU IMPLEMENT TESTING



PLANNING FOR OFFERING COVID-19 TESTING

Consider workflow, policies, and training involved:

- **Location**
- **PPEs**
- **Appointment-based**
- **Patient registration**
- **Procedure for screening**
- **Protocol for staff training**
- **Screening & consent form**
- **Take home testing information sheet/ FDA fact sheet**

WORKFLOW

Similar to medication order drop-off or processing, technicians can champion the workflow for COVID-19 testing:

- Patients make appointment online and provide information & answer screening questions
- Check accuracy of information provided by patients
- Call patient to confirm one day before appointment
- Perform contactless check in
- Have pharmacists double check accuracy of information
- Walk patients through each step for specimen collection
- Provide information & answer any questions patients may have

HOW DO YOU MARKET?

Pharmacists who are already testing patients said that it doesn't require much advertising

- Word of mouth
- Inform physicians' offices/nursing/ health system I.T. -> website
- Social media
- Local TV or radio stations/ local news
- Signs
- Phone greetings
- Tents

HOW PHARMACISTS & PHARMACY TECHNICIANS CAN HELP WITH COVID-19 TESTING?

ROLE OF PHARMACISTS

What can we do now and later?

- Identify individuals who need testing
- Provide POC COVID-19 testing
- Provide up-to-date vaccinations
- Prescribe medications through collaborative practice agreement
- Extend/Promote prescription delivery
- Convert 30-day to 90-day supply for maintenance medications
- Travel medicine clinic

ROLE OF PHARMACY TECHNICIANS

Identify opportunities to better assist pharmacists during the COVID-19 pandemic:

- Regular cleaning of pharmacy lab with sanitizers
- Order and restock PPEs
- Keep up-to-date on COVID-19 guidelines/ company protocols
- Help screen for patients who need influenza and pneumococcal vaccines, and COVID-19 testing
- Follow up with patient/ answer questions related to protocol

ROLE OF PHARMACY TECHNICIANS

Triage & conduct COVID-19 testing:

- Check accuracy upon initial registration
- Call patients for reminder of appointment
- Lead contactless check-in process
- Don't accept anyone not in his/her vehicle
- Walk patients through each step for sample collection
- Emphasize proper handling of testing supplies such as reagent tube
- Utilize dual drive through for sample collection and prescription drop-off
- Answer commonly-asked non-clinical questions from patients

COMMON COVID-19 TESTING QUESTIONS

Many questions that patients have are not clinical and can be handled by a technician.

- How long will the whole process take?
- How far do I need to insert to collect specimen?
- Does it hurt?
- How long will it take to get results?
- Can I get my results earlier?
- How accurate is the test?

COVID-19 TESTING SCAMS

Both pharmacists and technicians are in a good position to help protect patients from testing scams:

- Patients are asked to pay
- Counterfeit tests being sold on the street or door-to-door
- Getting an official test will affect immigration status
- Patients are offered a test that claims to be “FDA approved”¹⁷
- Phone calls requesting personal information (e.g. Social Security Number) for free test

STAYING UP-TO-DATE

FDA Issues Alert Regarding Accuracy Of Widely-Used Coronavirus Test

The [AP](#) (8/17, Perrone) reports, “Potential accuracy issues with a widely used coronavirus test could lead to false results for patients, U.S. health officials warned.” On Monday, “the Food and Drug Administration issued the alert...to doctors and laboratory technicians using Thermo Fisher’s TaqPath genetic test.” According to “regulators...issues related to the equipment and software used to run the test could lead to inaccuracies.”

COVID-19 TESTING IN OTHER COUNTRIES

Pharmacists can currently provide COVID-19 testing in limited countries including:

- US
- Canada ¹⁹

¹⁹. Canadian Pharmacists Association. COVID-19 Information and resources. 2020 <https://www.pharmacists.ca/advocacy/covid-19-information-for-pharmacists/>

COVID-19 TESTING IN OTHER COUNTRIES

Various countries are utilizing pharmacists skillset to respond to the Pandemic

- Australia ²⁰
 - Implementing a Covid-19 clinical pharmacist
- UK ²¹
 - Hundreds of pharmacies providing finger-prick antibody testing

²⁰. Nguy, Jenny et al. "The role of a Coronavirus disease 2019 pharmacist: an Australian perspective." *International journal of clinical pharmacy* vol. 42,5 (2020): 1379-1384. doi:10.1007/s11096-020-01067-4"

²¹. The Pharmaceutical Journal, Vol 305, No 7939, online | DOI: 10.1211/PJ.2020.20208182"

WHAT'S IN THE PIPELINE

Influenza and Strep POC tests are already available and this is a good time to look into starting those as well:

- Dual tests that screen for influenza and COVID-19 are being developed
- Stay tuned!

TAKE HOME MESSAGES



TAKE HOME MESSAGES...

- Molecular tests are more applicable at settings such as a lab
- Serology tests can be employed at outpatient/ Am Care settings
- Application for a certificate of waiver is not complicated but can take time
- Protocol include:
 - Staff training
 - Patient screening & consent form
 - Patient education sheet

TAKE HOME MESSAGES...(CONTINUED)

- Areas to consider before implementation of POC tests
 - CLIA waiver
 - Government regulations
 - PPEs
 - Marketing
 - Reimbursement
 - Potential risks for staff

TAKE HOME MESSAGES...(CONTINUED)

- Role of pharmacists
 - Order & perform tests as a provider and bill insurance
 - Front-line provider
- Role of pharmacy technicians
 - Be familiar & fully engaged in workflow
 - Explain step-by-step instructions
 - Collect samples
 - Be familiar with frequently-asked questions and answer non-clinical questions as appropriate

BACK TO ASSESSMENT QUESTIONS...

ASSESSMENT QUESTION #1

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- A. True
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- B. Change gloves between each patient
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**SESSION
CODE:**



**PHARMACY
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Disneyland
RESORT