



COLLEGE of AMERICAN  
PATHOLOGISTS

# Navigating Implementation of SARS-CoV-2 Testing

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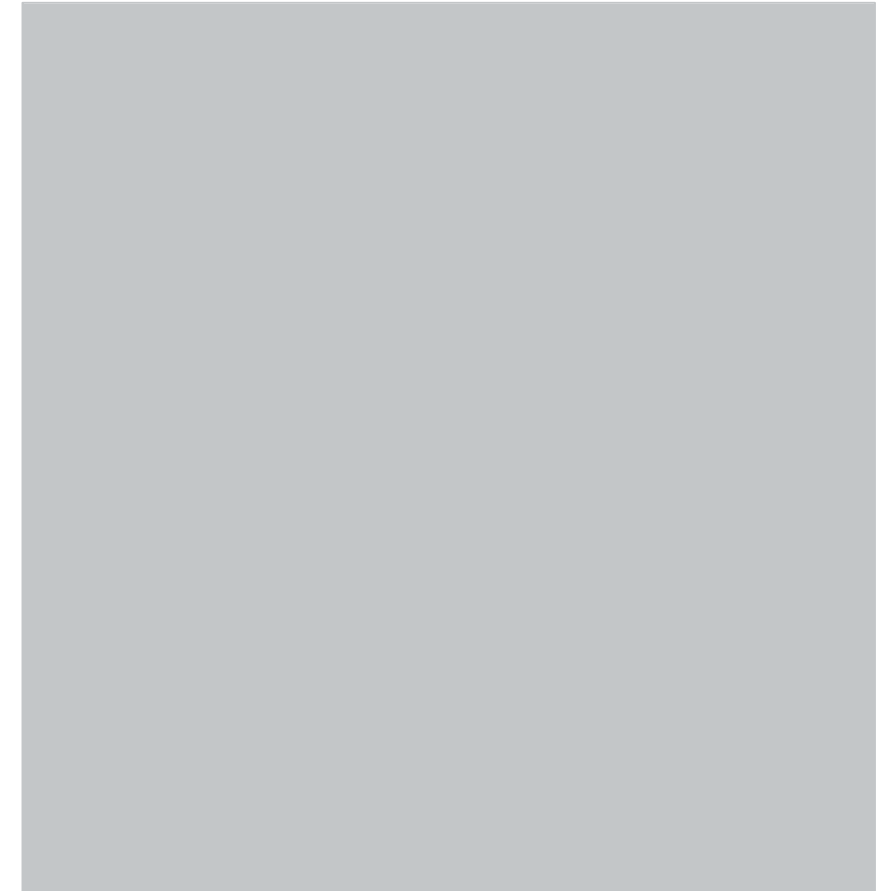
Earle Collum, MD, FCAP  
Richard Scanlan, MD, FCAP

June 11, 2020

# Today's Presenter

## Earle Collum, MD, FCAP

- Earle Collum MD, FCAP, is the Division Medical Director for Mid-America as well as the site medical Director for the Phoenix and Denver regional labs at LabCorp. Previously, he was the Medical Director of St Joseph's Hospital and Medical Center's Department of Pathology and Laboratory Medicine in Phoenix. He was also President of the Medical Staff. Dr. Collum is Board Certified in Anatomic and Clinical Pathology. He is an active member of the CAP and has performed over 200 inspections. Currently he is the chair of the CAP's Complaints and Investigations Committee. He was recognized with a CAP Lifetime Achievement award in 2017.



# Today's Presenter

## Richard M. Scanlan, MD, FCAP

- **Richard M. Scanlan, MD, FCAP, is vice chair of clinical pathology, professor of pathology, and director of transfusion medicine at Oregon Health Sciences University (OHSU) in Portland, Oregon. He is board certified in anatomic and clinical pathology. He is actively involved in the Portland pathology community and serves as laboratory director for Planned Parenthood of Oregon. Dr. Scanlan is a CAP governor and has been active in the CAP's Laboratory Accreditation Program since 1986. Currently he is the chair of the CAP Council on Laboratory Accreditation.**



# Objectives

- Common COVID-19 Terminology
- Current COVID-19 Tests
- Verification/validation of COVID-19 testing
- Quality monitoring and personnel qualifications
- Biosafety for COVID-19
- General COVID-19 testing questions

# Terminology

# Emergency Use Authorization (EUA)

- **What is an EUA?**
  - Legal mechanism used by the FDA
  - Allows use of unapproved medical products during a public health emergency
  - Used when there are no adequate, approved, and/or available alternatives

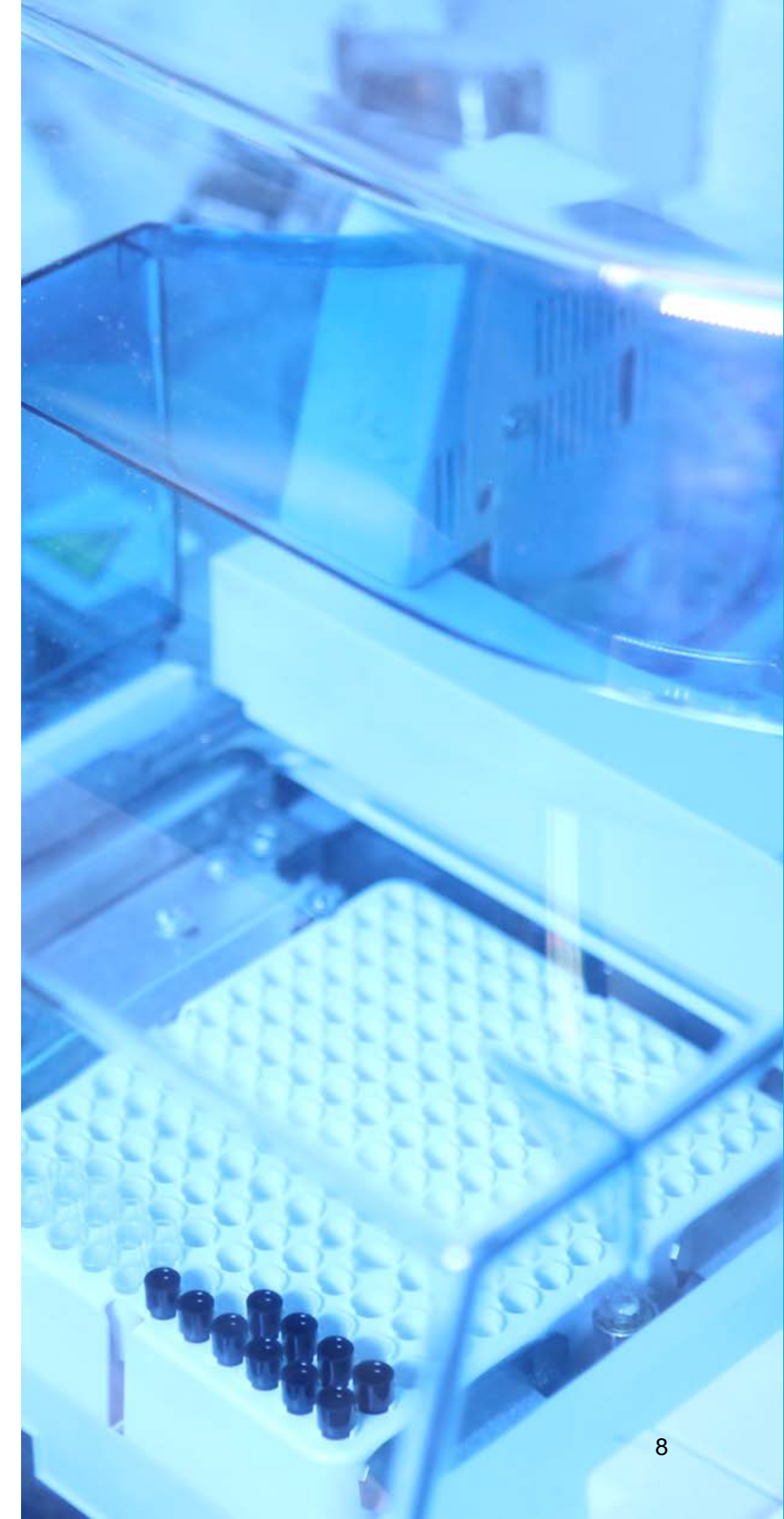
# Emergency Use Authorization (EUA) – cont'd.

- How is an EUA different than FDA-clearance or approval?
- What about laboratories outside of the US?



# Laboratory-Developed Test (LDT)

- What is an LDT?
  - Test is performed by the clinical laboratory in which it was developed wholly or in part AND
  - Test is neither FDA cleared/approved





# Laboratory-Developed Test (LDT) – cont'd

- Is an EUA considered an LDT?
- Can my laboratory develop an LDT for COVID-19 testing?

# Test Complexity

- What is the complexity of tests used for COVID-19?
  - Prior to obtaining EUA
  - Without EUA (following FDA policy)
  - With EUA



# Test Complexity cont.

- Are there any waived tests?

\* A complete listing of EUA tests and the complexity of each is found on the [FDA website](#).

# Types of Testing

# Types of COVID-19 Testing

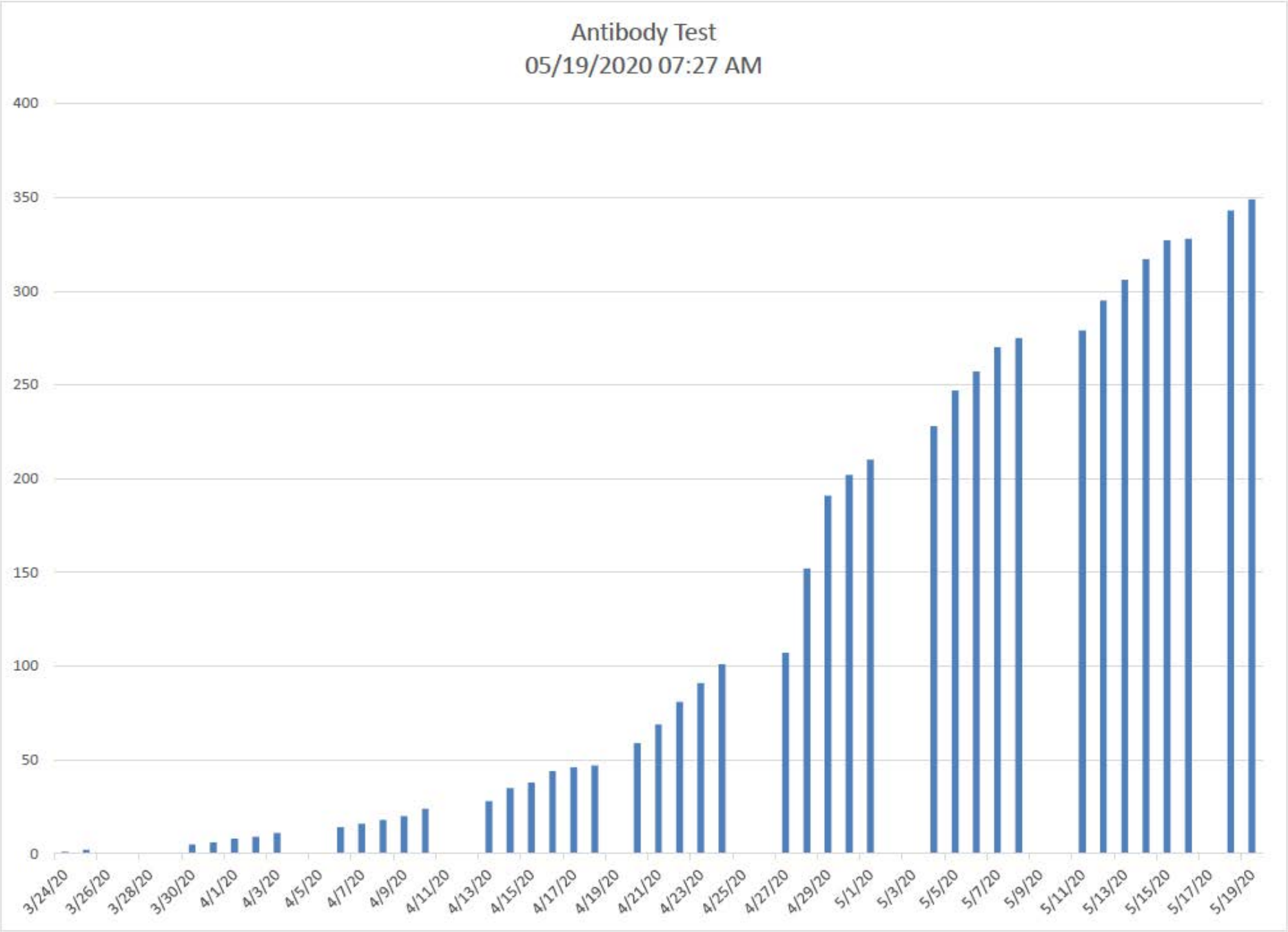
- What types of COVID-19 tests are available?
  - Molecular diagnostic tests
  - Serological tests
  - Antigen detection tests

\* Helpful references

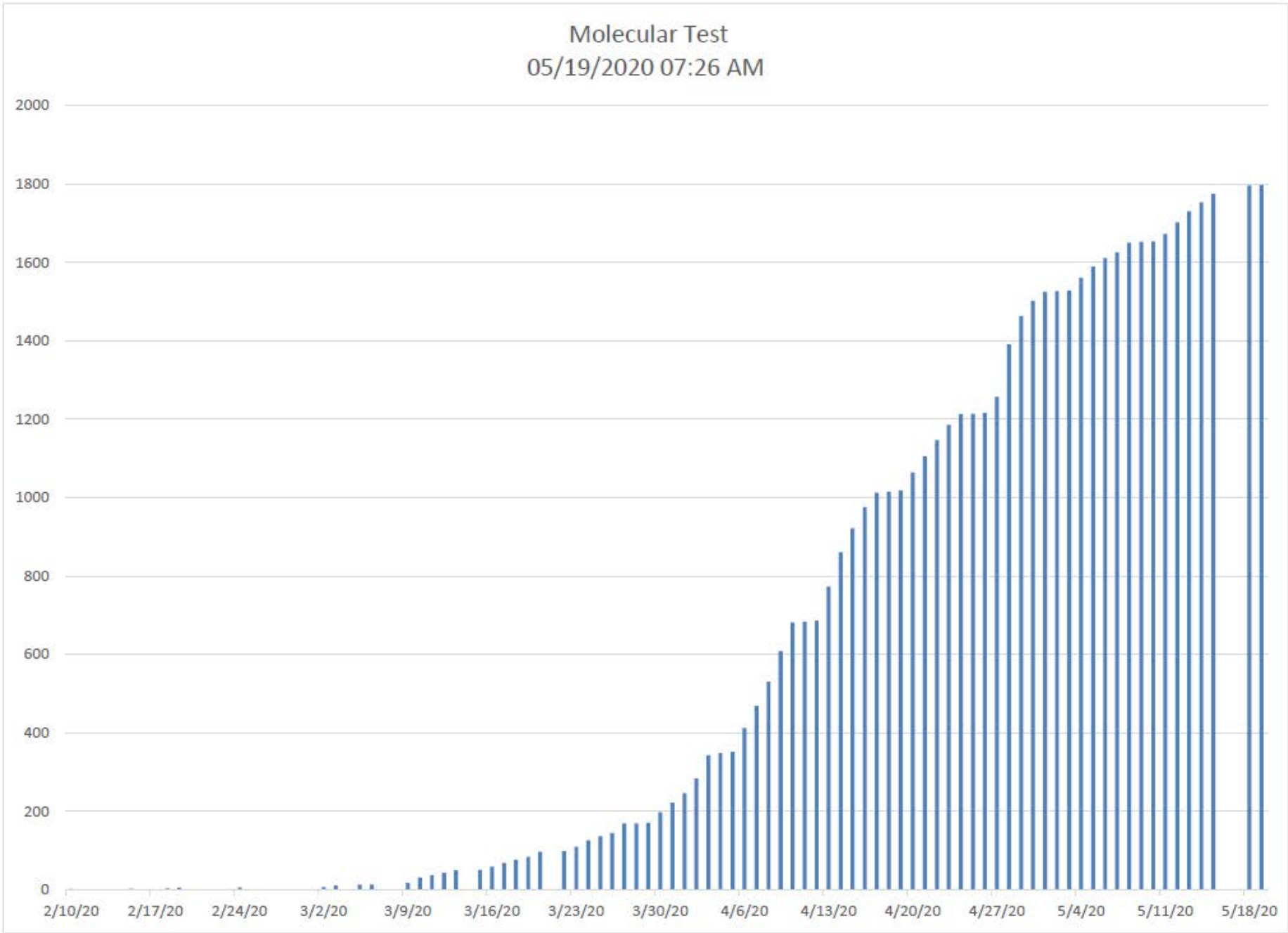
[The College of American Pathologists: Clarifying Tests for COVID-19](#)

[FDA Policy for Coronavirus Disease-19 Tests During the Public Health Emergency](#)

# Serology Testing



# Molecular Testing





# Test Method Validation and Verification

# Test Method Verification (COM.40300/COM.40325)

What does my laboratory need to do before using an EUA test?

- Laboratories using EUA tests must verify
  - Accuracy
  - Precision
  - Reportable Range
  - Analytical Interferences



# Test Method Validation (COM.40350)

What does my laboratory need to do to develop its own test?

- **Laboratories using LDTs must validate**
  - Accuracy
  - Precision
  - Reportable Range
  - Specificity
  - Sensitivity
  - Analytical Interferences

# Modifications to EUAs

**What does my laboratory do if there is a shortage of essential component needed to perform the testing?**

- **Supply shortages have required alternatives**
  - Swabs
  - Transport media
  - Testing materials
  - Equipment

# Modifications to EUAs cont.

- FDA provides recommendations on alternatives in their [FAQs](#)
- Laboratories must validate other alternatives (bridging study)



# Quality Monitoring

# Proficiency Testing (PT) – COM.01500

- Does the CAP have PT available for COVID-19 testing?
  - Molecular-based testing
  - Serologic testing
  - Antigen testing



# Proficiency Testing (PT) – COM.01500

- Perform alternative performance assessment if the laboratory is not performing PT
  - \* Order CAP PT products in the online store or by contacting the CAP at 800-323-4040

[Home](#) > [Laboratory Improvement](#) > [Proficiency Testing](#) > SARS-CoV-2 Proficiency Testing Programs

## SARS-CoV-2 Proficiency Testing Programs

As laboratories expand patient testing capabilities for detection of or exposure to the novel coronavirus (SARS-CoV-2), we have introduced new proficiency testing (PT) programs to support your efforts.



### Enroll Today

Place your order today to ensure material availability.

[Order SARS-CoV-2 Serology \(COVS\)](#) →

[Order SARS-CoV-2, Molecular \(COV2\)](#) →

# Quality Control and IQCP

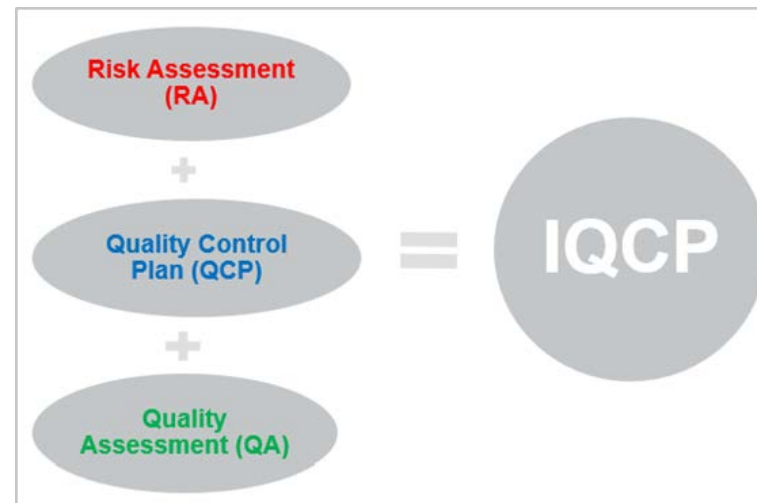
- **What type of QC does my laboratory need to do for COVID-19 testing?**
- **Does my laboratory need to implement an IQCP for COVID-19 testing?**

# Quality Control and IQCP cont.

- **Waived tests (authorized for the patient care setting)**
  - Follow manufacturer's instructions for internal/external QC – IQCP does not apply

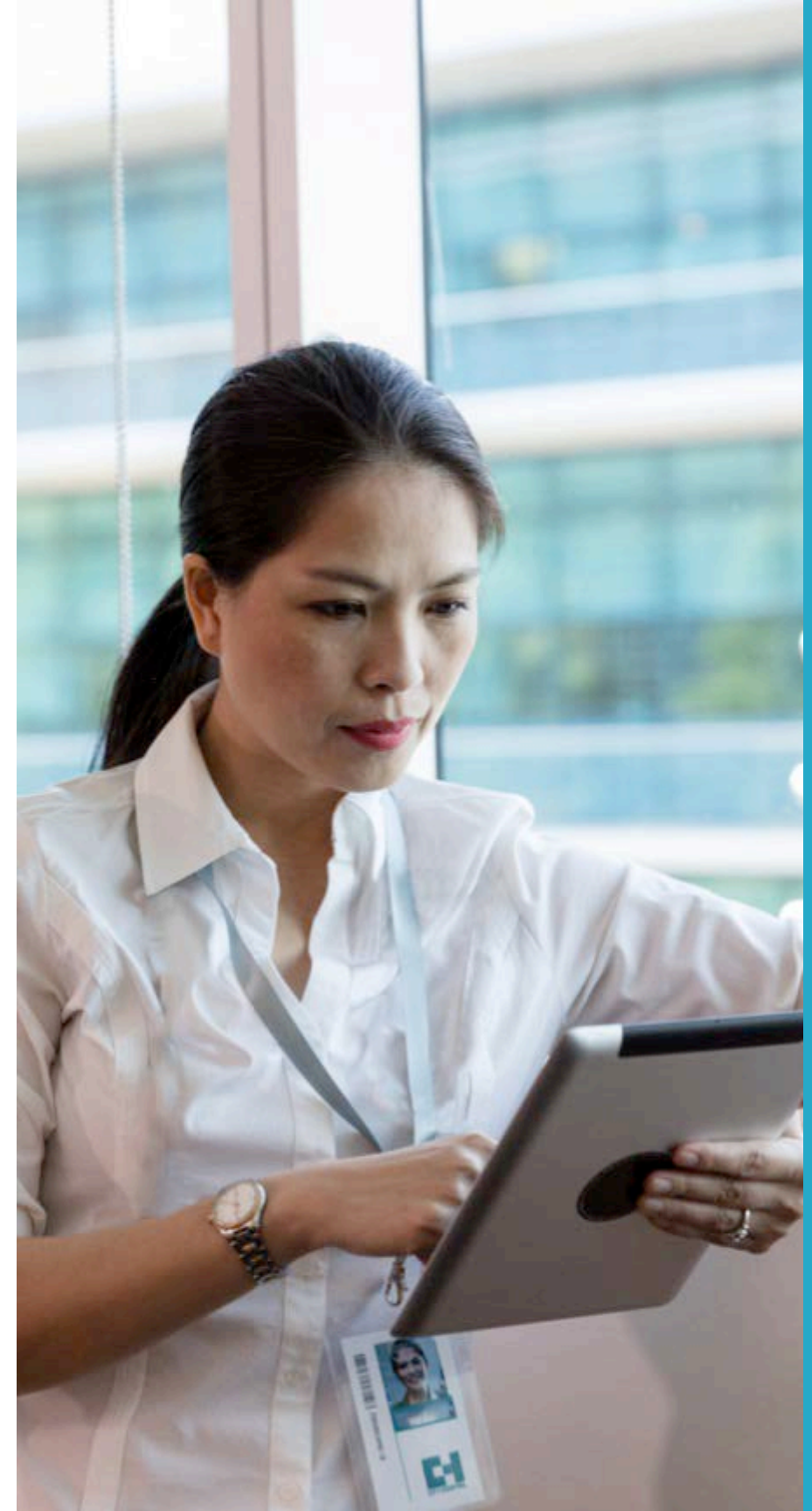
# Quality Control and IQCP cont.

- **Moderate and high complexity tests**
  - If manufacturer instructions define reduced external QC frequency, follow instructions – no IQCP required
  - If manufacturer's instructions do not define reduced external QC frequency
    - Perform positive and negative external QC each day of use **OR**
    - Develop and implement an IQCP



# Nucleic Acid Contamination and Molecular Testing

- Are there other types of quality monitoring my laboratory should do for COVID-19 testing?



# Nucleic Acid Contamination and Molecular Testing cont.

- **Laboratories must monitor and minimize contamination to prevent false positive results**
  - Perform wipe (environmental) tests
  - Monitor statistics
  - Investigate any physician inquiries
  - Use process controls to minimize risk of contamination
    - during collection, transport, processing and storage
    - Following instructions for handling waste (used test cartridges)



# Instrument/Equipment Maintenance

- What do we do if scheduled equipment maintenance was not done as scheduled due to the COVID-19 pandemic and vendors not being able to come onsite?





# Instrument/Equipment Maintenance – cont'd

- **The CAP recommends the following actions:**
  - Create a record to document and track the issue
  - Identify reasonable alternatives to complete the maintenance or perform an assessment of the affected equipment to determine continued use
  - Monitor continued performance through QC/function checks
  - Work with vendors to complete necessary maintenance
  - Retain records of the issue and resolution for at least two years

# Personnel

# Qualifications of Testing Personnel

What are the personnel qualifications to perform COVID-19 testing?

- **Personnel qualifications are based on the complexity of testing performed (GEN.54750)**
  - Review the FDA Letter of Authorization for your EUA assay to determine the complexity of the testing
    - For tests used without EUA, follow high complexity requirements
    - Verify that personnel performing the test meet the minimum qualifications defined in GEN.54750 based on test complexity
    - Maintain personnel training records to perform the test

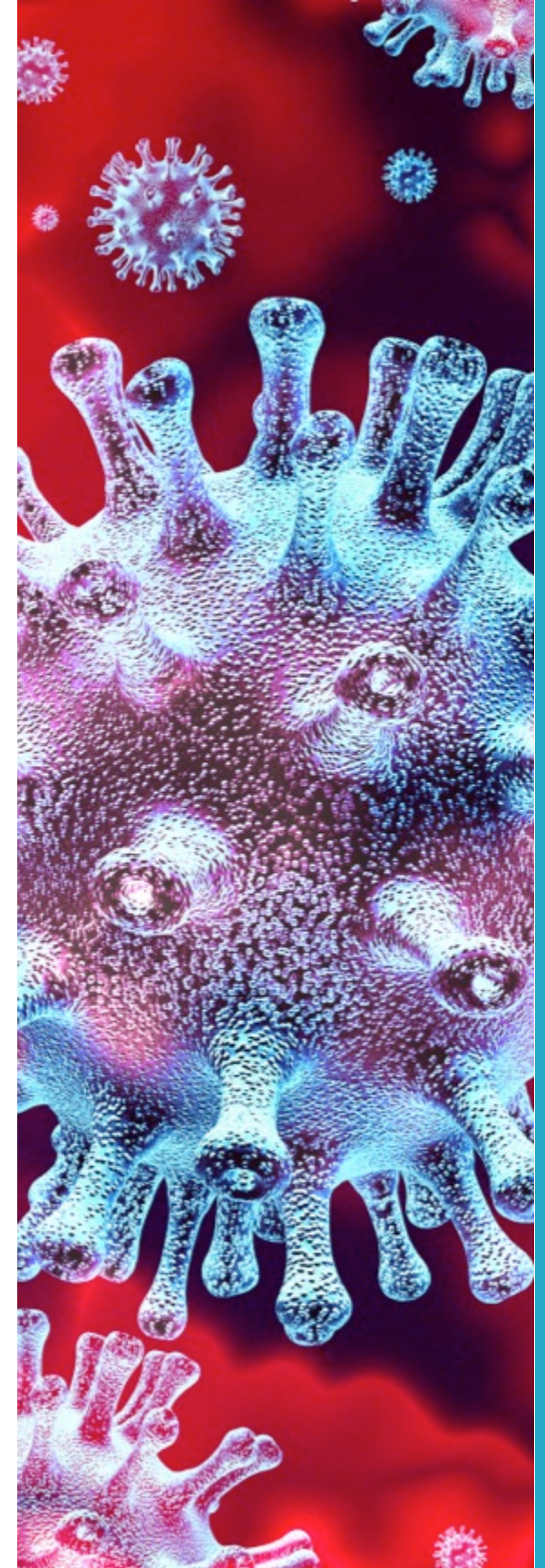
# Specimen Collection Personnel Qualifications

- Who is qualified to collect specimens for COVID-19 testing?
- There are no defined qualifications in the CAP checklists or CLIA regulations
  - Follow state-specific qualifications, as applicable
  - Train personnel to ensure adequacy of the specimen collected and safety of the procedure (for the patient and employee)

# Biosafety

# Personal Protective Equipment (PPEs)

- What precautions should be used when collecting specimens from suspected or confirmed COVID-19 patients?



# Personal Protective Equipment (PPEs) cont.

- For specimen collection, CDC recommends:
  - N95 or higher-level respirator (or face mask if respiratory is not available)
  - Eye protection
  - Gloves
  - Gown



# Personal Protective Equipment (PPEs) cont.

- What precautions should be used when handling/testing specimens from suspected or confirmed COVID-19 patients?



# Personal Protective Equipment (PPEs) cont.

- For handling/testing, CDC recommends
  - Standard precautions including gloves, lab coat/gown, eye protection
  - For procedures with a **high likelihood to generate droplets or aerosols**
    - Surgical mask/face shield
    - Other physical barriers
    - Centrifuge covers/caps
    - Biologic safety cabinets

\* Visit the [CDC website](#) for the most current guidance

# Q & A'S on COVID-19 Testing

# Recommended Testing

- **Does the CAP recommend any specific COVID-19 testing for my laboratory setting?**
  - 1) test volumes
  - 2) turn around times needed
  - 3) current testing platforms in use within your laboratory
  - 4) testing personnel qualifications
  - 5) PPE and biosafety measures available for staff
  - 6) availability of supplies to begin and maintain patient testing

# Pooling of Samples

- Can my laboratory perform testing on pools of specimens for COVID-19 molecular-based testing?
- \* Contact the FDA Division of Microbiology for additional information on regulatory approval for modifying an EUA
  - (301) 348-1778
  - [CDRH-EUA-Templates@fda.hhs.gov](mailto:CDRH-EUA-Templates@fda.hhs.gov)

# Reporting of Results for Multiple Platforms

- My laboratory is using three different instrument platforms for COVID-19 molecular testing and each uses different reporting language. We use the same reportable result for all three platforms?



# Specimen Collection Devices

- **We have two different instruments for COVID-19 EUA molecular testing. The manufacturer's instructions for one includes the use of nasopharyngeal swabs and nasal swabs. The other only includes nasopharyngeal swabs. Can we validate the second test to allow the use of nasal swabs on both instruments?**

# Transporting and Shipping Specimens

- How should suspected or confirmed COVID-19 specimens be transported within a facility?
- What are the requirements for packaging and shipping specimens from suspected or confirmed COVID-19 patients?



# Temporary Suspension of Testing

- Due to the COVID-19 pandemic, my laboratory temporarily suspended some of its testing. What do we need to do restart it?

# Disclaimers in reporting

- Are specific disclaimers required on reports for EUA COVID-19 tests?

# Competency Assessment

- With the current challenges due to the public health crisis, is any leniency being given to performing competency assessment?
- How can we perform direct observation with social distancing?



# New Reagent Lot Testing

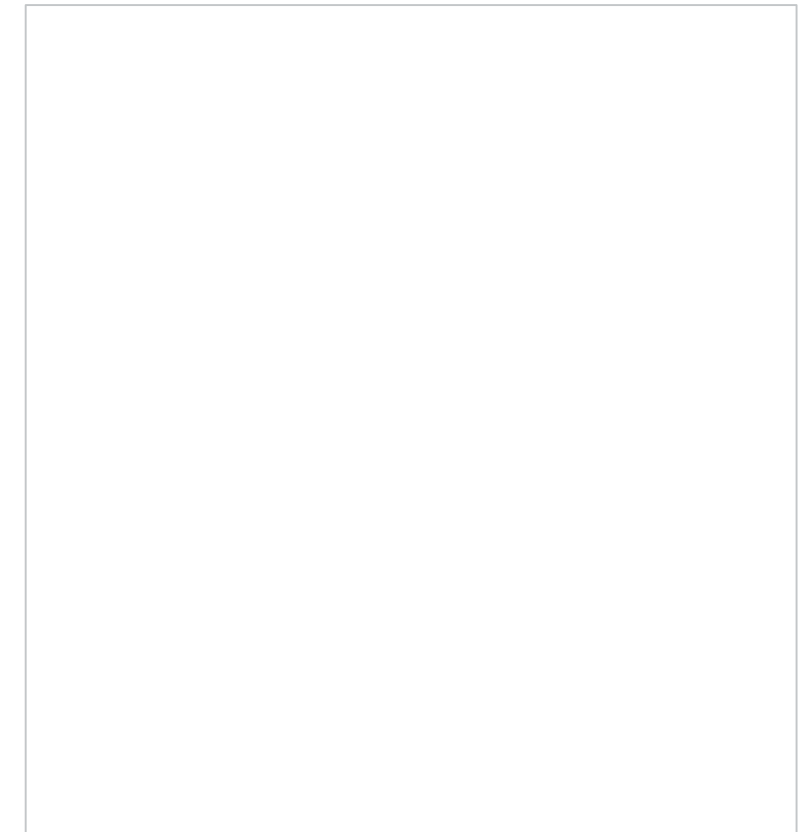
- **My laboratory has two identical instruments for COVID-19 testing. Do we need to do new reagent lot testing on both?**
- **If my laboratory has the same instrument as our satellite laboratory, can we QC the new lot and send it to the other site to use also?**

# Problems with EUA Tests

- **What actions should my laboratory take if we notice problems with the EUA test it is using, such as complaints from physicians about false positives or negatives?**

# Laboratory Director Sign Off

- **My laboratory director has been unable to come into the laboratory to sign off on proficiency testing, test validation/verification studies, and other items. Can we obtain the signature electronically?**



# Missed/Delayed Duties

- **Because some staff were furloughed or unable to come to work, there are some instances where my laboratory missed performing required duties (eg, instrument maintenance, PT, method comparison) or performed them later than required. Will my laboratory be cited during our next inspection?**



# Inspection Delays

- My laboratory's CAP inspection window is due to open in August 2020, should we expect any delays?
- My laboratory's anniversary date was in May 2020 and we have not had our inspection yet. Are we still considered CAP-accredited?





# Direct to Consumer Testing (DTC)

**Can we perform DTC for COVID-19 testing?**


- **State by State**

# Workplace or Corporate Testing

**Can we test for a corporation and report results back to its HR department?**



# Comprehensive COVID-19 Resources to Help You Navigate the Public Health Emergency

 COLLEGE of AMERICAN  
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All Sites |

Member Resources ▾    Advocacy ▾    Laboratory Improvement ▾    Learning ▾    Protocols and Guidelines ▾    Publications ▾

### COVID-19 Information

CAP Statement on the Current Role of Serologic Testing for SARS-CoV-2

[Read More](#)

### COVID-19 Updates

Access recent updates on COVID-19

[See the Updates](#)

# Clarification and Compliance Guidance

## Technical Specialists (Medical Technologists):

- Clarify checklist requirements
- Offer guidance on compliance
- Educate on best practices
- Field > 2,000 calls per month

Available via phone or email at [accred@cap.org](mailto:accred@cap.org).





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