

Understanding COVID-19 Testing – The Key to the Return of College Sports

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Housekeeping Items

***All attendees other than panelists will remain on "listen-only" mode for the entire discussion.**

If you want to speak:

- Use the “Raise Hand” function and Hannah will recognize you and unmute you individually
- Message Hannah directly in the “Questions” tab – these questions will be read aloud, and attendee will remain anonymous
- Write a question in the “Chat” box – please note that anything written in the “Chat” box will be seen by the entire audience

Meet the Speakers



Joyce Gresko
Partner
Alston & Bird, LLP



Sean Murray
President
Eurofins



David Morgan
President
Eurofins Transplant
Diagnostics



Joyce Gresko, Partner, Alston & Bird LLP

Topics Covered

- Where are COVID-19 tests performed?
- What are different types of tests and what are they used for?
- What specimen types can be used?
- Who gets test results?
- Who pays for COVID-19 testing?
- What to think about when engaging a lab for testing

Types of tests and their uses

rt-PCR

- Detects genetic material from the virus that causes COVID-19
- Used to diagnose an active/acute case of COVID-19 – “snapshot”
- Performed in a reference laboratory (e.g., Eurofins) or in a physician’s office/hospital

Antigen

- Detects protein fragments of the virus that causes COVID-19
- Used to diagnose an active/acute case of COVID-19 – “snapshot”
- Performed in a physician’s office/hospital

Antibody or “serologic”

- Detects antibodies to the virus that causes COVID-19
- Used to determine whether someone has been exposed to the virus
- IgM – one of the first antibodies to be created – may be present in acute phase of infection
- IgG – appears 2-3 weeks after infection and remains in the blood after infection has passed
- Performed in a reference laboratory or in a physician’s office/hospital



Validated Specimen Types



Test results and who gets them

- **Rt-PCR test—**

- Positive/negative or detected/not detected
- Also may be “indeterminate”
- Positive or detected means the virus has been detected in the sample and the individual is presumed to be contagious – even without symptoms

- **Antigen test—**

- Positive/negative
- Positive means the antigen has been detected in the sample and the individual is presumed to be contagious
- Negative means the antigen has not been detected – but it does not mean the individual is not infected

- **Antibody test—**

- Detected/not detected
- Also may be “indeterminate” or “equivocal”
- Detected means the antibody has been detected in the sample and the individual has been exposed to the virus in the past
- Beyond that...stay tuned.

- **CLIA regulations:** results can be released to “authorized persons,” the treating healthcare provider who is using the results, and the patient

- **HIPAA regulations:** test results can be released to the person who was tested, the physician using the results, and to another individual designated by the person tested, if the request is in writing, is signed by the individual, and clearly identifies the designated person and where to send the copy of the results.

The testing landscape today

- A handful of commercial laboratory companies are doing the majority of rt-PCR and antibody testing in the U.S.
 - Testing v. specimen collection
- Testing is available not only for diagnostic purposes, but also for return-to-work and return-to-school purposes and to identify “hot spots”.
- Most capacity and supply shortages have been addressed... for now.

Compare...

Reference Laboratory

- **High accuracy** for rt-PCR tests
- **Thousands** of tests performed each day
- **24-48 hour** turn-around time (depending on logistics)
- Collection supplies provided, no capital investment

Point of Care

- **Lower accuracy** for rt-PCR tests
- **100** tests/day/reader max
- **5-6 minutes** for positive result, **14 minutes** for negative result
- Capital investment for test reader, purchasing supplies

Check for the Good Housekeeping Seal of Approval...

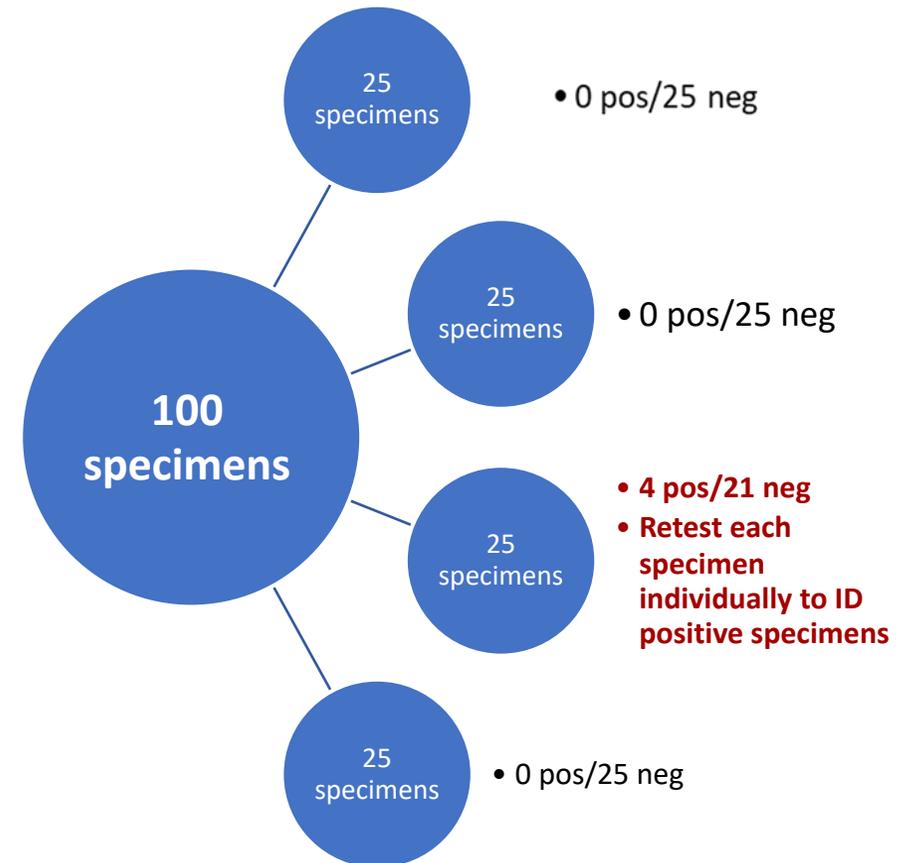


- Laboratory holds a valid **CLIA certificate**
- For the duration of the Public Health Emergency—
 - **rt-PCR tests** – Emergency Use Authorization (EUA) from the FDA or state authorization
 - **Antigen tests** – EUA or state authorization
 - **Antibody tests** – EUA or state authorization or validation by a CLIA-certified lab
- FDA pulled 40+ low-quality antibody tests from the market already...

A word about “specimen pooling”

- “Specimen pooling” is a laboratory technique used to conserve reagents and save money.
- Most useful to screen groups expected not to be infected (e.g., not symptomatic).
- Specimens are tested in batches; if no virus is detected in the batch, a conclusion may be drawn that no one whose specimen was included currently has COVID-19.
- FDA guidance on specimen pooling released June 16.

Example with 100 specimens:



Total tests without specimen pooling: **100**

Total tests with specimen pooling: **29**



Who pays for testing? It depends...



Diagnosis



Screening:
Return-to-the-Field
Return-to-Work
Return-to School



Public Health

Who pays for testing?

“CDC Director Says ‘Yes’ to Free Coronavirus Testing After Intense Questioning”

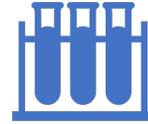
- Slate.com, March 12, 2020

“There ain’t no such thing as a free lunch.”

- Robert Heinlein, *The Moon is a Harsh Mistress*

- **By law**, health insurers are **required** to pay for rt-PCR, antigen, and antibody testing for COVID-19 – the law is agnostic regarding whether a patient must be symptomatic or the test’s intended use.
- **In reality**, more and more insurers are issuing coverage policies that **exclude** antibody testing altogether and rt-PCR testing used for screening purposes or for asymptomatic people.
- Congress has appropriated **some money** to pay for testing, but not much.
- Many employers and schools are **paying out of pocket**, if they can.

Issues to consider in your contract with a lab



Representation by lab that it is CLIA-certified, will use only those tests authorized by the FDA, will comply with HIPAA



Who is responsible for scheduling and performing specimen collection, obtaining consents and authorizations, shipping costs, etc.



Turn-around-time guarantees, availability of testing capacity on certain dates



When, how, and to whom will results be reported



Whether lab must get your permission to disclose publicly that it is doing testing for you



Who pays, how, how much

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Thank you and GO BLUE!!!



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