WELCOME TO THE LATEST LEAD1 ASSOCIATION VIRTUAL FORUM:

"RETURNING TO THE COURTS AND CLASSROOMS: CONSIDERATIONS FOR COLLEGE BASKETBALL IN THE AGE OF COVID-19"

PRESENTED BY eurofins

FEATURING:

Joyce Gresko
Partner
Alston & Bird LLP
Moderator

David Morgan
President
Eurofins Transplant Diagnostics

Troy Ayers
Vice President of Sales
Eurofins Microbiology

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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

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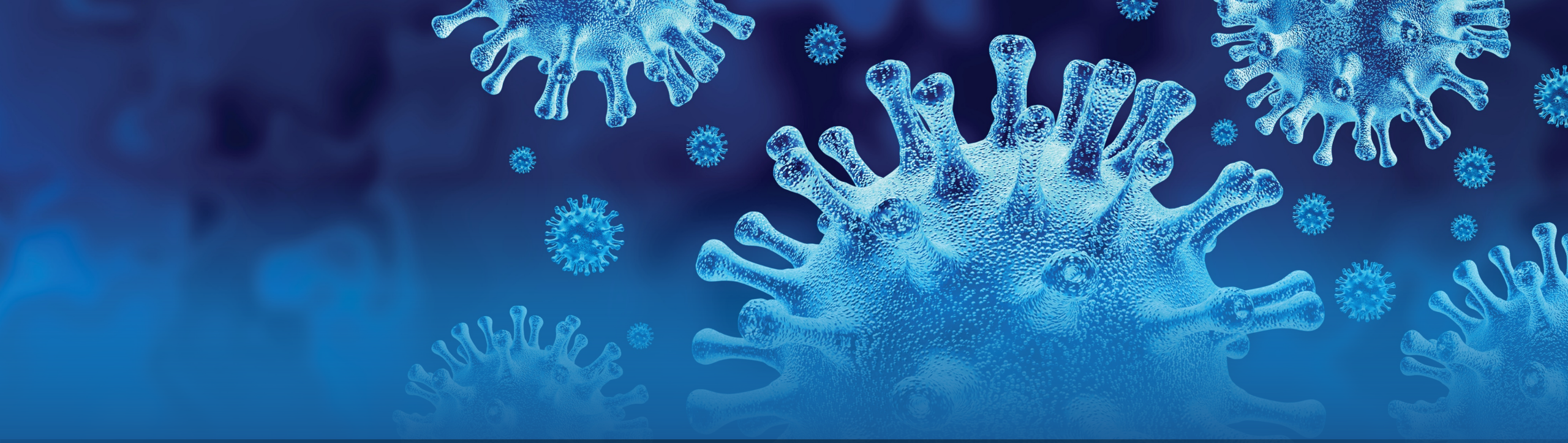

Returning to the Courts and Classrooms– Considerations for College Basketball in the Age of COVID-19

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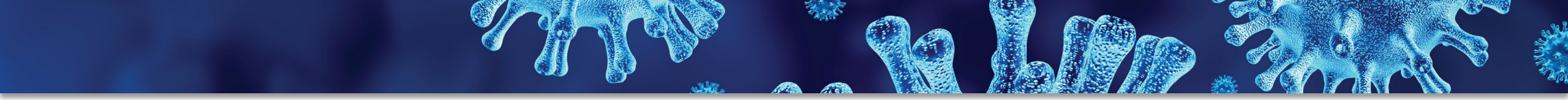


Topics Covered

- 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

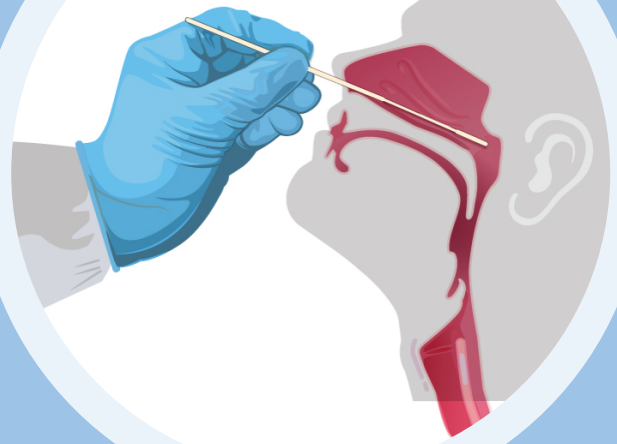
- Detects genetic material from the virus that causes COVID-19
- Used to diagnose an active/acute case of COVID-19 – "snapshot"
- Performed in a reference laboratory (*e.g.*, Eurofins) or in a physician's office/hospital

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.

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The testing landscape today

- Better than it was! But not as robust as it could be.
- Commercial labs, hospital labs, and public health labs all have leaned in.
  - 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”.
- Capacity and testing supply shortages ebb and flow with outbreaks, and can affect turn-around time for results.

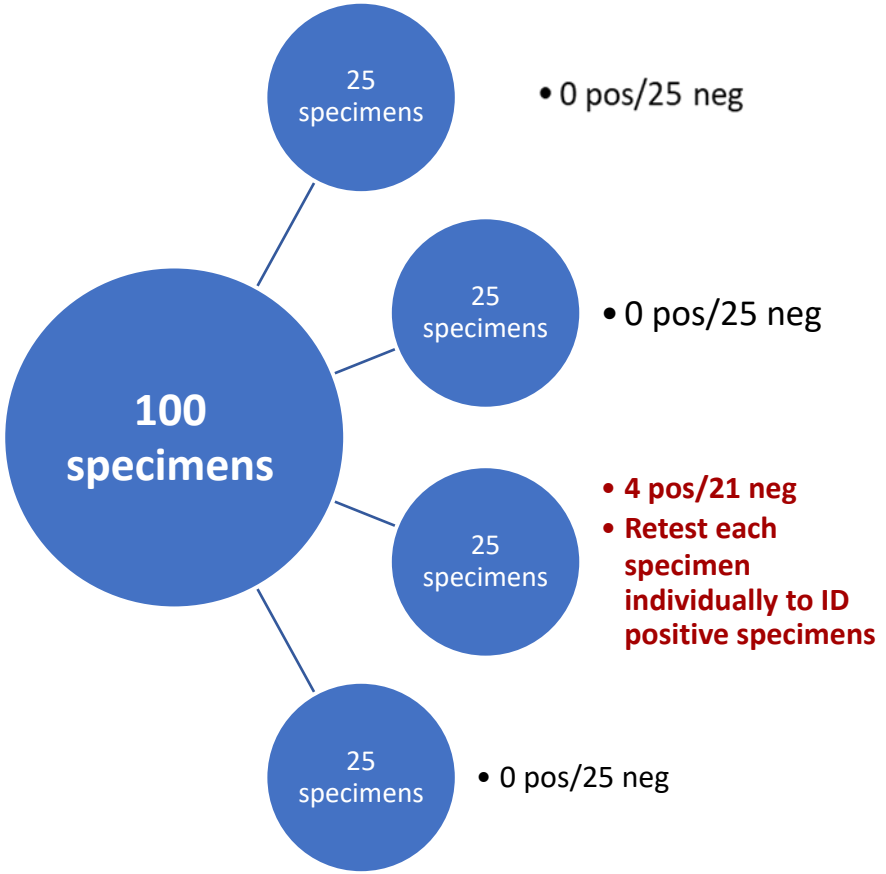
Check for the Good Housekeeping Seal of Approval…

- 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.
- 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.
- Most useful to screen groups expected not to be infected (*e.g.*, not symptomatic). Becomes a less viable technique when the community incidence of infection exceeds 5%.

Example with 100 specimens:



Total tests without specimen pooling: **100**
Total tests with specimen pooling: **29**

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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**

- **Congress required** health insurers 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.
- **Trump Administration issued** guidance that limits health insurers' responsibility to testing for those who are symptomatic and those with known or suspected exposure to an infected person. "Return to work" and "return to school" are excluded from the coverage mandate.
- Congress has appropriated **some money** to pay for testing, but not much. Some states are using their own funds or funds from the federal government to pay for some testing.
- 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

A final word…

"Testing must be an AND strategy, not an OR one. Rapid testing AND masking. Rapid testing AND social distancing. Rapid testing AND vaccines. Testing is a belt-and-suspenders approach that adds incrementally to safety. Belts and suspenders only work, though, when you're wearing pants."

Why Trump's Rapid-Testing Plan Worries Scientists, The Atlantic (Oct. 9, 2020)

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Thank you!

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