

# The Importance of Laboratory Developed Tests (LDTs) in Diagnosing COVID-19

MODERATOR **Patricia Jones, PhD**

SPEAKERS **Dennis Dietzen, PhD**, and **Carolee Estelle, MD**

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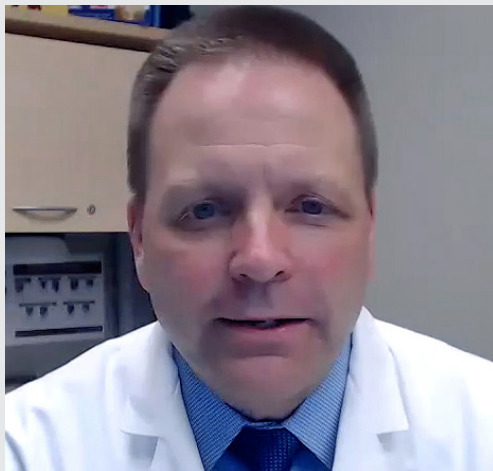


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MODERATOR

**Patricia Jones, PhD**

Medical Director of Laboratories, Children's Medical Center;  
Professor of Pathology, University of Texas Southwestern Medical Center, Dallas, TX



SPEAKERS

**Dennis Dietzen, PhD**

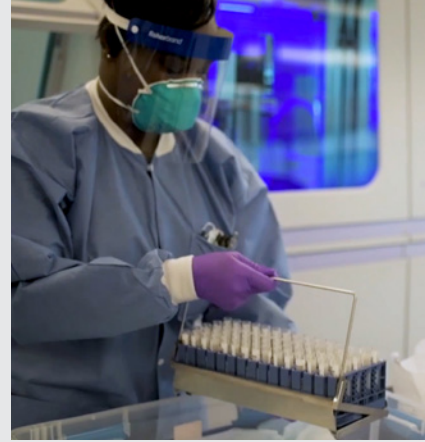
Medical Director of Laboratories, St. Louis Children's Hospital;  
Professor of Pathology & Immunology, and Pediatrics, Washington University School of Medicine, St. Louis, MO



**Carolee D. Estelle, MD**

Interim Chief of Healthcare Epidemiology, Parkland Health & Hospital System;  
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University of Texas Southwestern Medical Center, Dallas, TX





## The Importance of LDTs in Diagnosing COVID-19

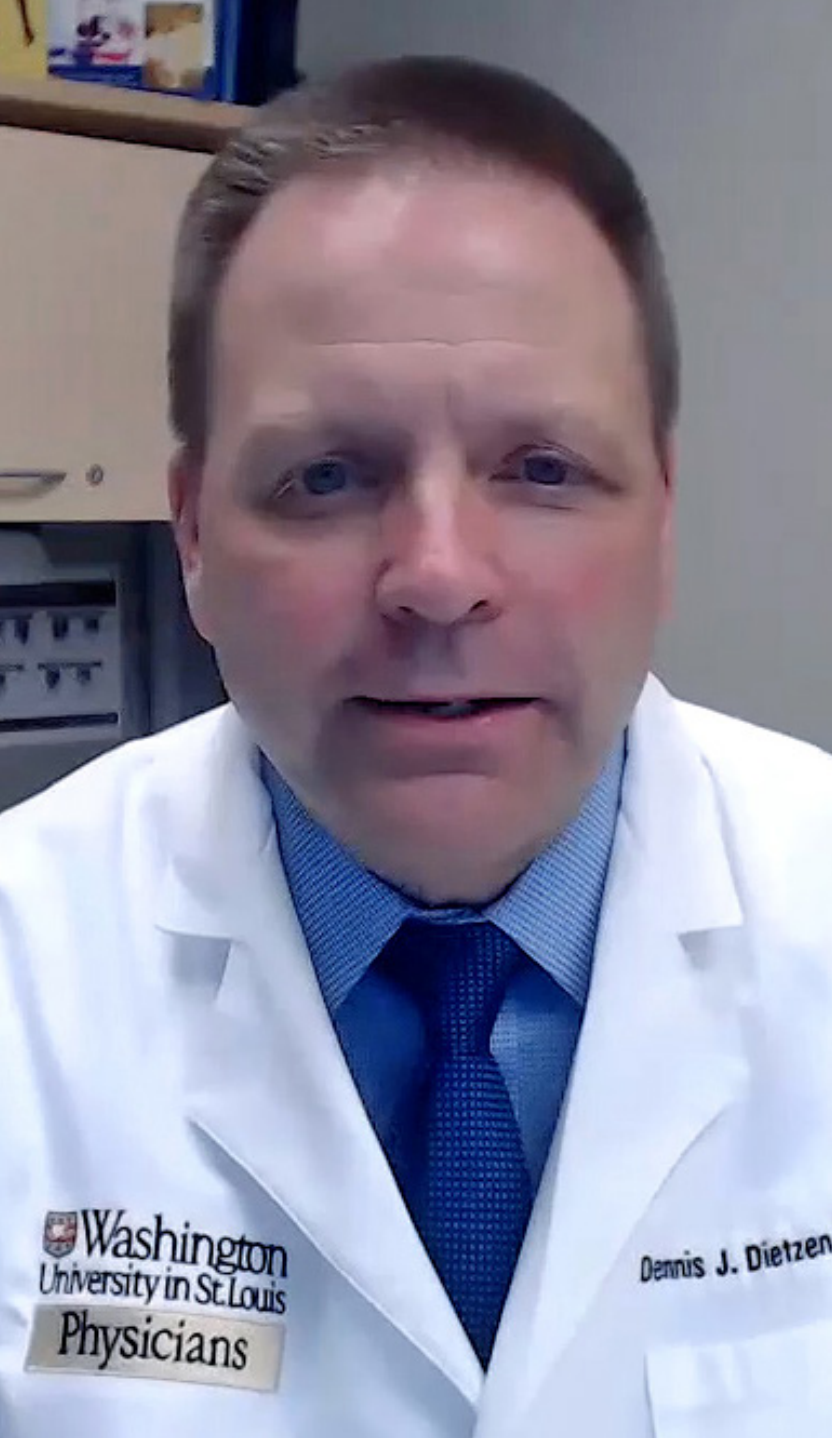
- ▶ Introduction | Dr. Patricia Jones
- ▶ Scope of briefing
  - > COVID-19 put in context
  - > Central role of labs
  - > Need to ensure access
  - > Understand regulatory environment
  - > Importance to patient care



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# COVID-19: Development, Use, and Regulation of Laboratory Developed Tests (LDTs)

## **Dennis Dietzen, PhD**

Medical Director of Laboratories, St. Louis Children's Hospital;  
Professor of Pathology & Immunology, and Pediatrics,  
Washington University School of Medicine, St. Louis, MO



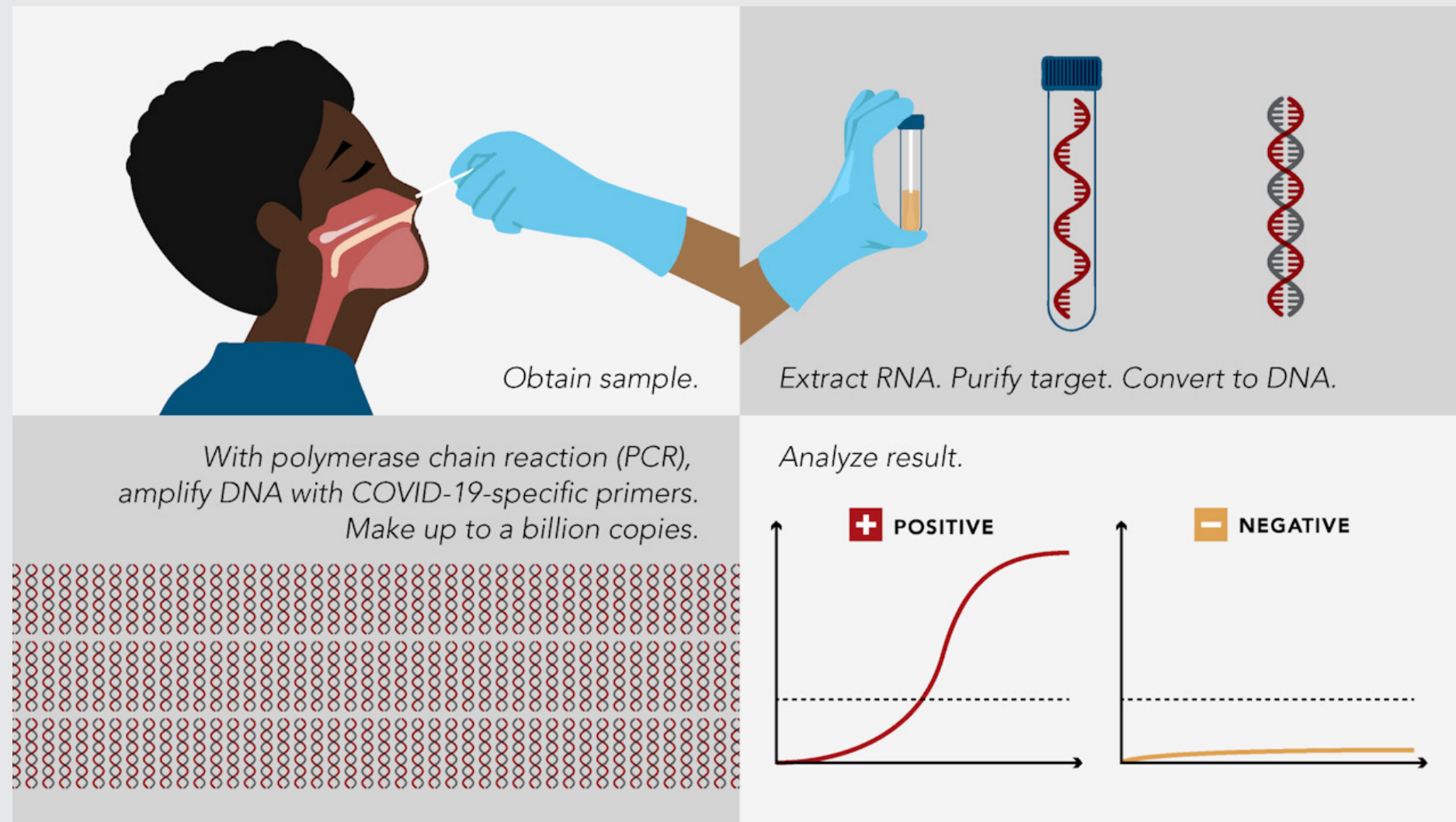
# Overview of Laboratory Developed Tests (LDTs)

- ▶ What are LDTs?
- ▶ Who develops LDTs?
- ▶ Where are LDTs performed?
- ▶ What conditions rely upon LDTs?



► What are laboratory developed tests (LDTs)?

- > Precision
- > Accuracy
- > Reportable range
- > Reference range
- > Sample integrity/stability
- > Clinical accuracy



- ▶ Who develops laboratory developed tests (LDTs)?
  - > Bachelor's Degree
  - > MD or PhD
  - > Residency
  - > Fellowship
  - > Board Certification
  - > Maintenance of Certification



- ▶ Where are laboratory developed tests (LDTs) performed?
- ▶ What conditions rely upon LDTs?
  - > Outdated/obsolete tests
  - > Rare conditions
  - > New conditions
  - > New infections
  - > New disease markers
  - > New technology





# Development of laboratory developed tests (LDTs)

- ▶ The need for COVID-19 LDTs
- ▶ Problems labs encountered
- ▶ Requirements to introduce COVID-19 LDTs



## How do laboratory developed tests (LDTs) help labs?

- ▶ Meet institutional needs
- ▶ Meet physician needs
- ▶ Meet patient needs





How are laboratory developed tests (LDTs) regulated?



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# Impact of Laboratory Developed Tests (LDTs) on Hospital Response to COVID-19

## **Carolee D. Estelle, MD**

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# Impact of COVID-19 Laboratory Developed Tests (LDTs) on Care Delivery

- ▶ Identification of cases
- ▶ Contact tracing
- ▶ Isolation of cases and exposed individuals



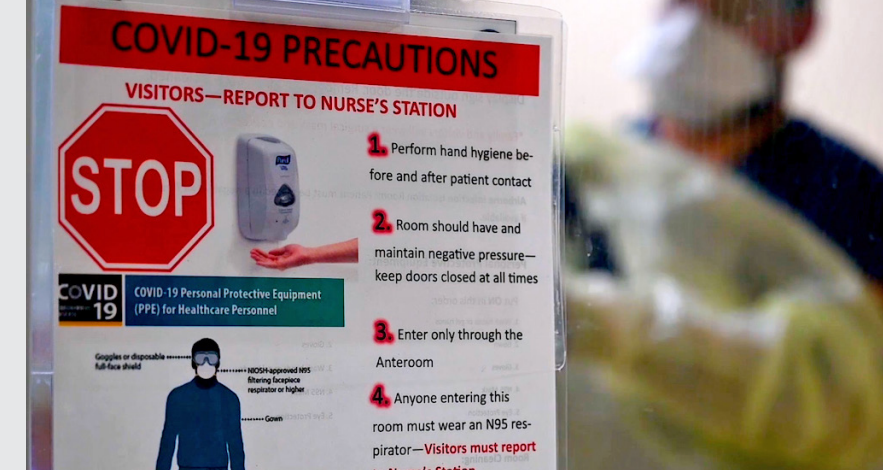
## Impact of COVID-19 on Hospital Operations

- ▶ Silent transmission from undetected/untested cases
- ▶ Exacerbate personal protective equipment (PPE) shortages
- ▶ Rapid appropriate patient placement



# Impact of COVID-19 on Workers and Patients

- ▶ Healthcare worker impact
  - > Indicate protective measures
  - > Indicate safe timing of procedures
  - > Identify infected healthcare workers and return to work
- ▶ Direct patient impact
  - > Start COVID-19 specific interventions
  - > Start clinical trials immediately



## Hospitals Before COVID-19 Laboratory Developed Tests (LDTs)

- ▶ Rationing of tests
- ▶ Delays in care
- ▶ Increased use of PPE





## COVID-19 Laboratory Developed Test (LDT) Benefits

- ▶ Rapid accurate diagnosis
- ▶ Ability to isolate and trace
- ▶ Streamline hospital operations
- ▶ Optimize PPE supplies



IF YOU HAVE QUESTIONS, PLEASE CONTACT

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THANK YOU

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