

Department of Medicine
Medical Grand Rounds

DATE: 6/29/2020
LOCATION: Education Resource Center Auditorium
TIME: 12:00 – 1:00 PM - Department Update/Grand Rounds Lecture
TITLE: “When failure is not an option: Development and deployment of accurate testing for a novel virus during a pandemic”
Speaker: Dr. Amy Mathers

For CME and MOC Credits as well as Instruction on How to Claim Credit please go to:

<https://med.virginia.edu/cme/learning/uvarss/medgrmoc/>

LEARNING OBJECTIVES:

- 1) Learn how to mitigate and interpret the various clinical, logistical, molecular and specimen factors which may affect the sensitivity of a SARS-CoV-2 diagnostic test
- 2) Understand how the Emergency Use Authorization act by the Food and Drug Administration has impacted test availability and accuracy

QUESTIONS:

1. The following factors will impact the sensitivity of SARS-CoV-2 viral RNA detection in a clinical sample
 - a) Anatomic site
 - b) Type of swab used
 - c) Molecular assay platform
 - d) Timing of the test collection in relation to symptoms
 - e) All of the above
2. The Emergency Use authorization act from the FDA impacts diagnostic test clearance by
 - a) Increasing the number of applications which can be reviewed at one time
 - b) Requiring more scrutiny of clinical laboratories during a pandemic
 - c) Allowing diagnostic test manufacturers to demonstrate test performance without a proven clinical track record
 - d) Helps fund the production of diagnostic tests in an emergency
3. A concern with widespread SARS-CoV-2 serologic testing in low prevalence area is the
 - a) Number of false negative
 - b) Number of false positives
 - c) Lack of sensitivity
 - d) Test availability
- 4) True or FALSE – There is no FDA cleared test for asymptomatic SARS-CoV-2 detection.
- 5) True or FALSE – Coronavirus serologic tests which did not have clearance for SARS-CoV-2 testing were allowed to be marketed for COVID-19 in the US.

DISCLOSURES: Dr. Mathers is an industry funded researcher/investigator and consultant for the following organizations: Accelerate Diagnostics, SeLux Diagnostics, VenatoRx.