Saliva Testing for SARS-CoV-2: A Game Changer and the Challenges That Come With It. **Salika M. Shakir**, **PhD**, **D**(ABMM), ARUP Laboratories and University of Utah School of Medicine, Salt Lake City, UT

Rapid and accurate diagnostic tests are essential for controlling the SARS-CoV-2 pandemic. Nasopharyngeal swabs (NPS) are considered the reference method for respiratory virus detection. However, the collection is relatively invasive and unpleasant, and puts healthcare workers at higher risk for disease transmission. In our study, we evaluated alternative diagnostic samples including patient self-collected saliva and anterior nasal swab (ANS) for SARS-CoV-2 detection. Our large, prospective study of symptomatic patients presenting to a drive-thru test center showed that self-collected saliva sample is equally effective compared to healthcare worker-collected NPS for detecting SARS-CoV-2. In comparison, self-collected ANS missed nearly 15% of infections. We demonstrated that saliva testing has a high concordance rate of greater than 95% compared with NPS. Moreover, saliva specimens are easier to collect, are non-invasive and therefore more appealing than NPS, and alleviate the global shortages for swabs and personal protective equipment.

Implementation of saliva collection for SARS-CoV-2 testing in the clinical laboratory comes with many challenges. We validated saliva diluted two-fold in transport media on three different nucleic acid amplification testing platforms. In our study and clinical testing, we observed an increased invalid rate (>3.5%) due to sample viscosity or complexity of the saliva matrix that may affect automated pipetting or internal control inhibition. A second dilution of the saliva specimen reduced the invalid rate, but this resulted in additional processing, increased time to results, labor, and overall cost of testing. Clinical laboratories will need to optimize collection and processing before implementing saliva for SARS-CoV-2 testing.

Objectives:

- 1. To understand the advantages of saliva as an alternative specimen type to nasopharyngeal swab for SARS-CoV-2 testing
- 2. To highlight the challenges associated with saliva testing in the clinical laboratory
- 3. To understand the need for clinical laboratories to optimize saliva collection and processing for high volume testing