Comparison of the ID NOW and Accula Point-of-Care Assays for the Detection of SARS-CoV-2

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Background:

In December 2019, a novel coronavirus was found to cause respiratory infections in Wuhan Province, China. The virus rapidly spread throughout Wuhan Province, then to other parts of China and eventually the world. The illness ranged from asymptomatic carriers to acute respiratory distress (ARDS). The virus was subsequently named SARS-CoV-2 and the respiratory disease, coronavirus disease-2019 (COVID-2019). In March 2020 the World Health Organization (WHO) classified COVID-2019 as a pandemic (4).

In response to the pandemic, the Food and Drug Administration (FDA) approved several platforms under emergency use authorization (EUA). These platforms do not have full FDA approval and may be used for COVID-19 testing temporarily in a clinical laboratory until the manufacturer receives full FDA clearance for use in the U.S (3).

Two point of care (POC) platforms with current EUA approval are the ID NOW COVID-19 (Abbott) and the Accula SARS-CoV-2 tests (Mesa Biotech) (1,2). Both tests are designated as CLIA waived complexity. POC's play a vital role in the diagnosis of COVID-19, especially in laboratories and clinics where testing including molecular assays and serology is not available.

The ID NOW COVID-19 test is an automated qualitative assay that is EUA approved for use on nasal, nasopharyngeal (NP), and oropharyngeal specimens (2). This assay utilizes isothermal nucleic acid amplification technology for the qualitative detection of SARS-CoV-2 viral nucleic acids within 15 minutes. The Accula SARS-CoV-2 test is also a qualitative assay and is approved for use on nasal specimens. The test uses reverse-transcription polymerase chain reaction followed by lateral flow and provides results within 30 minutes.

Currently the Clinical Microbiology Laboratory at Ascension Michigan Laboratory Services has validated and utilizes the ID NOW COVID-19 assay to analyze Ascension St. John (ASJ) emergency department (ED) and inpatient specimens. While this assay has a high positive predictive value, the sensitivity and negative predictive value are low. Furthermore, acquisition of test kits is limited due to large demand and limited supplies.

Purpose:

The purpose of this study is to compare SARS-CoV-2 results from clinical specimens on the ID NOW and the Accula systems. If the Accula system is comparable or demonstrates superior test parameters including sensitivity, then this assay may potentially be used throughout Ascension, especially in markets which have limited access to testing. This in turn will assist in improving turnaround times for COVID-19 results and facilitate reinstating elective surgeries.

Methods:

All testing will be conducted in a College of American Pathologists (CAP)- accredited biosafety level-2 laboratory with restricted access. All patient specimens will be manipulated under a certified biosafety level-2 cabinet.

The testing personnel for the ID NOW will be medical laboratory technologists and technicians in the clinical microbiology laboratory who have previously been trained and are competent under Clinical Laboratory Improvement Amendments (CLIA) guidelines at performing the ID NOW COVID-19 assay. Testing personnel for the Accula assay will consist of a lead medical laboratory scientist and the technical director of the microbiology laboratory, a Ph.D. level scientist.

The ASJ microbiology laboratory validated the ID NOW COVID-19 assay in April 2020. The protocol for testing is located on PolicyStat and can be accessed using the link below. https://ascension-lab.policystat.com/policy/7897941/latest/. Currently when rapid COVID-19 tests are ordered on ASJ ED patients or inpatients one nasal swab is collected by the clinical staff. The swab is then placed in a sterile conical tube and delivered to the microbiology laboratory where the COVID-19 test is run STAT on the ID NOW. Specimens used for ID NOW testing cannot be re-used for repeat ID NOW testing or any other laboratory testing due to the initial genomic extraction step which requires use of the entire swab.

Patients with orders for rapid COVID-19 testing who have consented to participate will be included in the study. We will also include patients who have been confirmed positive for COVID-19 by PCR, swabs will be collected from these patients after obtaining consent. For patients with orders for rapid COVID-19 testing, one additional clinical specimen, anasal specimen will be collected from the patient at the same time as the initial specimen for the ID NOW. For patients who were confirmed positive by PCR, two additional swabs will be collected: one for the ID NOW and one for the Accula test. Swabs for both ID NOW and Accula testing will be provided to the clinical teams in pre-packaged kits with directions on specimen collection and transport. After collection, all swabs must be labeled with a specimen label (per current protocol). Following consent and collection of specimens, specimens will be sent to the microbiology laboratory. The ID NOW COVID-19 assay will continue to be performed STAT.

If laboratory testing personnel are available, the additional swab will be eluted in a buffer tube as recommended by the manufacturer and then utilized for the Accula SARS-CoV-2 assay. In the event that immediate testing cannot be performed, however, swabs will be stored at room

temperature for two hours or 2-8°C for up to 24 hours prior to testing on the Accula (per manufacturer's guidelines). The Accula system is a new platform for the microbiology laboratory. The manufacturer of the Accula Test, Mesa Biotech, has been working in conjunction with the National Ascension Laboratory team to pilot this study in two Ascension Markets (Michigan and Florida). Five Accula analyzers will be sent to the Ascension Michigan Clinical Microbiology Laboratory along with SARS-CoV-2 test kits. The protocol for testing will strictly follow the manufacturer's instructions (https://www.fda.gov/media/136355/download).

If there is a discrepancy between the ID NOW and Accula test results, an additional specimen (nasal) will be collected from the patient, if possible (i.e. if the patient remains in-house) to confirm the COVID-19 results (unless the PCR results are already available). This additional test must be more sensitive than POCs. If the ASJ molecular laboratory is able to complete validation on the Roche 8800 which will be arriving on April 24, 2020, the additional specimen will be run with the Roche COVID-19 assay. If not, specimens will be sent out to a reference laboratory for confirmation COVID-19 testing.

This study will evaluate accuracy (correlation) by comparing Accula results to the ID NOW, precision (reproducibility) by repeating select specimens with different users and on different analyzers, limit of detection by diluting commercial SARS-CoV-2 controls with a known concentration and cross-reactivity by testing known respiratory viruses (including influenza A, B and RSV) on the Accula.

Data Management and Analysis:

The electronic data from this study will be stored on the Ascension network which is a password-protected encrypted computer drive. All HIPAA guidelines will be followed to protect patient information. Only the lead technologist and technical director will have access to this file.

Currently, patient results from the ID NOW test are entered in the laboratory information system (LIS) by microbiology staff. Since the ID NOW is not interfaced with the LIS, patient reports are printed prior to verification and the hardcopies are stored in a binder in the laboratory. As required by CAP, these documents are stored securely in the laboratory for two years.

The lead technologist or technical director will enter the ID NOW results into the secure data file using the ID NOW hardcopy reports. The results from the Accula test and the Roche or send-out test, if performed, will be entered into the same spreadsheet using the same barcode number as the ID NOW. The only patient demographic information that will be recorded in the spreadsheet is the specimen barcode number for the ID NOW.

Any subsequent data shared with individuals other than the study testing personnel will not contain any patient identifiers, including the specimen barcode used as the identifier in the data collection file.

The following test parameters for the Accula will be calculated using the ID NOW as a comparator: sensitivity, specificity, positive-predictive value, negative predictive value.

Sample Size and Duration of Study:

The aim is to test 100 unique patients. The duration of this study will be determined based upon the number of specimens collected daily. We anticipate that sufficient specimens will be collected within a one-week time period.

Predicted Results:

The Accula SARS-CoV-2 test parameters including sensitivity, specificity, positive-predictive value, and negative predictive value will be similar or superior to the ID NOW COVID-19 assay.

References:

1. Accula SARS-CoV-2 Test IFU (EUA). Mesa Biotech, 2020.
2. ID NOW COVID-19 Assay IFU (EUA). Abbott, 2020.
3. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19). CDC. Last accessed 20 April 2020. https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html
4. Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases: Interim guidance. World Health Organization. 19 March 2020.