METHOD VERIFICATION SUMMARY REPORT

Detroit Health Department (DHD) in collaboration with Michigan
Department of Health and Human Services (MDHHS)

The Abbott ID NOW™ is authorized under the FDA EUA for use as a point-of-care test and is a CLIA-waived diagnostic test. While method verification of waived tests is not required by CLIA regulations, currently no publicly available, peer-reviewed scientific data exist on the specificity of the Abbott ID NOW™ for COVID-19 testing. A method verification plan was conducted to assess the Abbott ID NOW™ at the Detroit Health Department (DHD). DHD and Michigan Department of Health and Human Services (MDHHS) performed a verification on 49 specimens, showing 98% concordance with the 2019-nCoV Real Time RT-PCR diagnostic assay.

These are preliminary data that will be built upon with further verification testing on a larger and more robust sample population.

Method Verification Summary: Use of DHD Clinic Abbott ID NOW™ compared to 2019-nCoV Real-Time RT-PCR Diagnostic Panel assay performed by MDHHS Laboratory	

1.0 Scope

1.1 **Method Verification for:** Use of Abbott ID NOW™ instrument in comparison to the 2019-nCoV Real-Time RT-PCR Diagnostic Panel assay

1.2 **Department/Laboratory:** Detroit Health Department (DHD) Rapid Testing Clinic and Michigan Department of Health and Human Services Laboratory (MDHHS)

2.0 Overview of method verification plan:

2.1 50 Patients were swabbed with 2 swabs, with 1 swab per nostril

2.2 The 1st swab was placed back into the original wrapper and sealed in a biohazard bag. The bag disinfected with an alcohol wipe before being placed into a cooler with ice packs to maintain a temperature of 2-8°C for transport to MDHHS where they were placed in saline and tested by 2019-nCoV Real-time RT-PCR Diagnostic Panel assay within 24 hours of collection

2.3 The 2nd swab was placed directly into the Abbott ID NOW™ for processing in accordance with manufacturer's instructions

2.4 Individual results were printed with the label being cut (and later shredded) to remove patient identifiers, as well as the results, while unique Test ID remained for tracking and comparison

2.5 At the end of Abbott ID NOW™ testing, results with Test ID and all run parameters (excluding patient information) and were sent to MDHHS for comparison to the validated 2019-nCoV Real-time RT-PCR Diagnostic Panel assay performed by the MDHHS laboratory. This assay was used as the comparator or gold standard by which to assess the performance of the Abbott ID Now™

3.0 Summary of Results

Qualitative Characteristic	Number of samples tested	Performance
Accuracy (True Negatives and True Positives) *No 'Invalid' results were generated	49 samples (1 sample required instrument restart due to software freezing)	(48/49) x 100 = 98% of Abbott ID NOW™ results agree with RT-PCR results • 0 positive on both • 48 negative on both • 1 discrepant (negative on Abbott ID NOW™, positive by 2019-nCoV Real Time RT-PCR)

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4.0 Results

4.1 **Evaluation of discrepant results:** One discrepant result. MDHHS detected 2019-nCov RNA in one sample that was resulted as negative by Abbott ID NOW™ at the DHD Rapid Testing Clinic. This could be attributed to multiple variables including early onset of infection with viral RNA load below the detectable threshold for the Abbott ID NOW™ assay of 125 genomic equivalents/mL (see ID NOW™ COVID-19 Test Product Insert IN1).

4.2 **Limitations:** The population chosen for this study was a sample of individuals with clinic appointments only (first responders, and City of Detroit essential workers such as public transit and energy employees), and did not encompass more vulnerable populations experiencing ~25% positivity (e.g., nursing homes). In addition, the Abbot ID NOW uses a dry swab as opposed to a swab in VTM, which is the preferred sample for the 2019-nCoV Real-time RT-PCR Diagnostic Panel assay.

4.3 **Challenges in design:**

    a. **Specimen type (dry swab versus viral transport medium):** To assess the performance of the ongoing testing method at DHD Rapid Testing Clinic, in accordance with Abbott's newly revised protocol from 04/15/2020, direct nasal swabs were chosen as the sample type for this study (see ID NOW™ COVID-19 Test Product Insert IN1). Previously tested samples would require storage in Viral Transport Medium, and thus would not reflect the method used for current testing with the Abbott ID NOW™. Mitigation of this limitation included keeping swabs at 2-8C, and adding saline to the swab and testing within 24hrs.

    b. **Population:** To alleviate concerns of performing multiple swabs/rounds of swabbing on vulnerable populations, nursing homes were not used in this verification plan for sampling. This sampling population would have likely generated more positive cases and could be considered for future verification studies.

4.4 **Manufacturer limitations:** At this time there are not sufficient data on the effects of sample types, patient populations, time of collection relative to presence/absence of symptoms on test performance. Positive results are indicative of infection with 2019-nCoV, but do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history and epidemiological information.

5.0 Summary Report Approval

Approved By: Dr. Najibah Rehman Date: 05/01/2020

DHD Medical Director

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6.0 Instrumentation and QC data

Name/Model	Serial #	Location (Exam Room)	COVID ID Lot# (Test Base)	Positive Control Result (pass/fail) performed 04/26/2020	Negative Control Result (pass/fail) performed 04/26/2020
Abbott ID NOW™	20558F1B	1	M119032	Pass	Pass
Abbott ID NOW™	BBF98E1B	2	M119032	Pass	Pass
Abbott ID NOW™	AFAD8F1B	3	M119032	Pass	Pass

7.0 Training Requirements

7.1 Personnel performing the verification study were required to complete and document the following training elements on the Abbott ID NOW™ before testing independently

a. Observe previously trained personnel running 2 patient swab samples

b. Run 1 QC positive control swab successfully

c. Successfully perform swabbing and testing of 2 patient samples while being observed by trained personnel

Detroit Health Department Personnel trained	Date Completed
Kanzoni Asabigi	04/25/2020
Shantae Johnson	04/25/2020
Reena Thomas	04/25/2020

8.0 References

8.1 ID NOW™ COVID-19 Test Product Insert IN1 (https://ensur.invmed.com/ensur/contentAction.aspx?key=ensur.514295.S2R4E4A3.20200328.10292.4358420)

8.2 CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use (EUA) (https://www.fda.gov/media/134922/download)