

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2186024	(X3) Date Survey Completed 09/30/2021
Name of Provider or Supplier Meta Lab	Street Address, City, State 11512 Texland Blvd, Charlotte, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of manufacturer's instructions, review of 2020 and 2021 proficiency testing records, review of validation records, and interview with staff 9/30/21, the laboratory's procedure manual was not complete and current for the testing performed by the laboratory. Findings: 1. The laboratory's "PROFICIENCY TESTING" procedure states "... 5.2 Identify an approved proficiency provider with the capability of supporting each analyte, where available. With the Laboratory Director's approval, enroll the lab in an approved proficiency testing program. ... 5.2.1 For those analytes/tests where no commercially</p>

available approved proficiency testing is available, refer to Alternative Performance Assessment section. ..." Review of 2020 and 2021 proficiency testing records revealed the laboratory is enrolled in proficiency testing through CAP (College of American Pathologists). The laboratory also participates in an alternative assessment using blind samples supplied by another laboratory. During interview at approximately 9:45 a.m., the laboratory director confirmed that the procedure was not specific for the laboratory's proficiency testing activities.

2. The laboratory's policy "REPORTING COVID-19 LABORATORY RESULTS" states "5.1 How to report Laboratory data elements may be reported in the following ways: 5.1.1 Submit laboratory testing data directly to state or local public health departments according to state/or local law or policy. Data must be sent using existing reporting channels to ensure rapid initiation of case investigations, and concurrent reporting of results must be shared with the ordering provider or patient, as applicable. 5.1.2 Submit laboratory testing data to state and local public health departments through a centralized platform, where the data will then be routed to the appropriate state and local authorities and routed to the CDC after removal of personally identifiable information according to applicable rules and regulations. 5.1.3 Submit laboratory testing data through a state or regional Health Information Exchange (HIE) to the appropriate state or local public health department and then to CDC as directed by the state. ..." Review of the document "MetalabDX PHA Reporting Process" revealed a process for using a cloud based platform called AIMS to send COVID-19 laboratory results to states: "... results are sent to APHL through an HL7 ORU pipeline. APHL examines the message contents to determine the appropriate reporting agency and routes it accordingly..." During interview at approximately 1:00 p.m., the laboratory director verified that the lab uses a third party system to report COVID-19 results. She confirmed that the policy did not provide specific instructions for the process used by the laboratory to report COVID-19 test results using a third party platform.

3. The laboratory's "SARS-CoV-2 COVIDNow 96 Saliva Now" procedure states "... 7.10 Storage Once received, specimens are stored for 14 days at -80 degrees C. Samples may be thawed for re-testing once they have been frozen. ..." The "SalivaNow SARS-CoV-2 Assay Kit rRT-PCR Diagnostic Panel Instructions for Use" state on page 7 "... Storing Specimens Specimens can be stored at 2-8 degrees C for up to 72 hours after collection. If a delay in specimen processing is expected, store specimens at -70 degrees C or lower. ..." During interview at approximately 11:15 a.m., the general supervisor confirmed that the laboratory stores saliva specimens for up to 72 hours after collection then disposes of them. She verified the laboratory does not freeze or store COVID-19 specimens beyond 72 hours. Review of validation documents revealed the laboratory's validation of the SalivaNow SARS-CoV-2 Assay Kit rRT-PCR Diagnostic Panel did not include stability studies for saliva specimens stored at temperatures of -70 degrees C or stored for periods of time beyond 72 hours. The laboratory's "SARS-CoV-2 COVIDNow 96 Saliva Now" procedure had not been updated to reflect the laboratory's current practice for specimen storage.

4. The laboratory's "Referral of Specimens to Outside Labs" procedure states "... 2. Scope: Applies to the referral of specimens by the laboratory to another laboratory for testing in case the laboratory is unable to conduct testing ... 5.3 Referral testing will be performed by a CLIA certified lab in good standing using similar instrumentation. Turnaround time will be determined by the testing lab. Any variations will be investigated. ..." During interview at approximately 11:45 a.m., the laboratory director stated that if the laboratory was unable to test, specimens would be stored as long as possible and then they would find a lab to send them to for testing. During the exit interview at approximately 1:45 p.m., the managing partner of the lab stated there were two labs performing similar testing that were contracted to provide reference lab services in the event the lab was unable to perform testing. The laboratory's procedure did not specify the process used to refer

specimens to an outside laboratory, and did not include contact information for the outside laboratories contracted by the laboratory to provide testing.