

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0707800	(X3) Date Survey Completed 04/21/2022
Name of Provider or Supplier American Health S Llc DbA American Health	Street Address, City, State 15712 Sw 41 St Suite 16, Davie, FL	
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
D0000	A complaint survey for 2022003587 was conducted on 4/20/2022 to 4/21/2022 at American Health Associates. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 record review and interview, the laboratory failed to have OPTI SARS-CoV-2 RT-PCR and Lyra Direct SARS-CoV-2 Assay procedure for retesting indeterminate COVID-19 specimen tested and failed to retest the indeterminate specimen following manufacturer instructions. Findings Included: Review of Standard Operations Manual</p>

revealed there was no procedure for testing retesting indeterminate COVID-19 specimen for OPTI SARS-CoV-2 RT-PCR. Review of OPTI SARS-CoV-2 RT-PCR instructions for use stated the following "Invalid Sample: SARS-CoV-2 (FAM)= No Ct value, Internal Control (HEX)= > 36. Absence of an amplification curve in the FAM and H E X (VIC) channels indicates an invalid result for the sample. Invalid - Specimens with an invalid pool result must be tested individually prior to reporting a result. However, in instances of an invalid run, repeat testing of pooled specimens may be appropriate depending on laboratory workflow and required result reporting time." Review of Lyra Direct SARS-CoV-2 Assay Instructions for Use stated the following "Invalid - Detector: SARS-CoV-2= No Ct detected, Detector: Process Control=No Ct detected. Interpretation of results: No SARS-CoV-2 viral RNA and no PRC RNA detected. Invalid test. Retest the same processed sample. If the test is also invalid, re-process and retest another aliquot of the same specimen or obtain a new specimen and retest." Review of 2021-2022 OPTI COVID-19 instrument printouts revealed on 7/02/2021 20 COVID-19 specimens received an invalid result (no Ct for internal and SARS-CoV targets) and were not retested for OPTI SARS-CoV-2 RT-PCR. Review of 2021-2022 Lyra Direct SARS-CoV-2 Assay instrument printout revealed on 6/22/2022 revealed 4 Covid-19 specimen were invalid (No CT Process Control and SARS-CoV targets) and not retest. for Lyra Direct SARS-CoV-2 Assay During an interview with the technical supervisor on 4/21/2022 at 4:59 PM, The technical supervisor confirmed did not have an OPTI SARS-CoV-2 RT-PCR and Lyra Direct SARS-CoV-2 Assay procedure for retesting indeterminate COVID-19 specimen tested and failed to retest the indeterminate specimen following manufacturer instructions. ` During an interview with the technician supervisor on 4/21/2022 at 4:59 PM, The technical supervisor confirmed did not have an OPTI SARS-CoV-2 RT-PCR and Lyra Direct SARS-CoV-2 Assay procedure for retesting indeterminate COVID-19 specimen tested and failed to retest the indeterminate specimen following manufacturer instructions. `