

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0992791	<b>(X3) Date Survey Completed</b>  04/06/2022
<b>Name of Provider or Supplier</b>  Americare Health Plaza Medical Center	<b>Street Address, City, State</b>  1805 Milton Road, Charlotte, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<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 laboratory records, review of laboratory's policies and procedures, and interview with the TC(technical consultant) 4/6/22, the laboratory's procedure manual was not complete and current for the testing performed. Findings: Review of laboratory records revealed the laboratory began testing for SARS-CoV-2 in January 2022 using the Indicaid Covid-19 rapid antigen test. Review of the laboratory's records also revealed the laboratory had manufacturer's IFU on file for the current test used, but the procedure manual did not include a step-by-step procedure for reporting SARS-CoV-2 test results to the public health authorities . During interview at</p>

approximately 11:05 a.m., the TC stated the laboratory is sending positive test results with patient demographics to the local health department and also scanning results into the patient's chart. She stated the laboratory is also scanning the negative test results into the patient's chart, but the local health department told the laboratory they do not need to report the negative test results. The TC confirmed there is no step-by-step procedure for how the laboratory is reporting the SARS-CoV-2 rapid antigen test results.

**D5407**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures and interview with the TC (technical consultant) 4/6/22, the laboratory failed to ensure that the procedure manual was approved by the current laboratory director. Findings: Review of the laboratory's policy and procedure manual revealed the current laboratory director had not approved the procedure manual on file. At approximately 9:30 a.m., the TC stated she could not locate the laboratory's current procedure manual and had obtained one from the facility's sister clinic. She confirmed the laboratory director had not approved and signed the procedure manual.

**D5783**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures and IQCP(individualized quality control plan), review of 2020, 2021, and 2022 patient and QC(quality control) records, and absence of documentation 4/6/22, the laboratory failed to document corrective action when QC was unacceptable for Candida, Trichomonas, and Gardnerella testing performed on the BD Affirm VPIII microbial identification test. Findings: Review of the laboratory's policies and procedures and IQCP revealed the laboratory runs a trivalent positive control(i.e. Candida Albicans, T. vaginalis, G. Vaginalis) and negative control with each new test kit. The laboratory's "BD Affirm VPIII Microbial Identification Test" procedure states for External Quality Control, "... When testing the trivalent positive control, verify that internal controls are both acceptable and interpret results as follows: If all three organism beads turn blue, all patient results can be reported. If the Candida bead does not turn blue, the entire QC run is invalid. No patient results can be reported...All QC failures must be investigated..." The laboratory's "Affirm VPIII Test logs(patient and control)" states, "...Positive control should yield positive results/negative controls should yield

negative results..." Random review of the 2020, 2021, and 2022 BD Affirm VPIII patient and QC logs revealed unacceptable results were obtained for the positive control tested on 11/29/21 for test kit lot # 1251549, expiration: 7/28/22. The positive control results were documented as "negative" for Candida, Trichomonas, and Gardnerella with no corrective action documented. Approximately 22 patients were tested with kit from 12/1/21 to 1/17/22.

**D5785**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, review of 2020, 2021, and 2022 temperature records and BD Affirm VPIII patient and QC(quality control), and absence of corrective action documentation 4/6/22, the laboratory failed to document corrective action when the room temperature and refrigerator temperature were outside the acceptable limits for the BD Affirm VPIII microbial identification test. Findings: The laboratory's "General Laboratory's Conditions" procedure revealed, "...If any readings are not within acceptable limits, appropriate remedial action will be taken and documented. Refrigerator: Acceptable limits: 35-46 degrees F(Fahrenheit) or 2-8 degrees C(Celsius). If temperature deviates slightly, adjust thermostat accordingly. If temperature indicates that integrity of stored items may be in jeopardy, move contents to another storage facility and have unit repaired...Room temperature: Acceptable limits: 72-82 degrees F..." The laboratory's "BD Affirm VPIII microbial identification test" procedure revealed, "...Storage of Reagent: The Affirm VPIII test kit is stable until the expiration date indicated on the box when stored at 2-8 degrees C...Procedure: 1. Verify that....reagents are at 22-28 C or 72-82 F and well mixed. Record the temperatures on the log sheets.... Automated processing NOTE: Before proceeding, ensure that all reagents are at 22-28 C. With each test run, verify that room temperature is between 22 and 28 C..." 1. Review of 2020, 2021, and 2022 BD Affirm VPIII patient and QC logs revealed the laboratory failed to document corrective action when the BD Affirm testing room temperature was outside the acceptable limits of 72-82 degrees F for the following: a. 5 days in September 2020 when room temperature was documented as 70 degrees F- (9/2, 9/7, 9/14, 9/16, 9/18). Approximately 9 patients were tested between 9/2/20- 9/18/20. 2. Review of 2020, 2021, and 2022 temperature logs revealed the laboratory failed to document corrective action when refrigerator temperature exceeded limits of 2-8 degrees C for the following dates: b. 10 of 15 days in August 2021- (8/13, 8/14, 8/16, 8/18, 8/20, 8/23, 8/25, 8/27, 8/28, 8/30); c. 15 of 16 days in September 2021- (9/3, 9/6, 9/8, 9/10, 9/11, 9/13, 9/15, 9/17, 9/20, 9/22, 9/24, 9/25, 9/27, 9/28, 9/29); d. 7 of 14 days in October 2021- (10/4, 10/6, 10/8, 10/9, 10/11, 10/13, 10/15).

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document

all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's IQCP(individualized quality control plan), review of QA(quality assessment) records, and interview with the TC(technical consultant) 4/6/22, the laboratory failed to review the effectiveness of the laboratory's IQCP for the BD Affirm VPIII microbial identification test. Findings: Review of the laboratory's BD Affirm VPIII IQCP and QA records revealed the laboratory had not reviewed the effectiveness of the IQCP since last done 3/31/17, a period of approximately 60 months. During interview with the TC at approximately 10 a.m., she confirmed the IQCP should be reviewed annually as part of the QA plan but it had not been done.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of personnel records, review of the TC(technical consultant) delegation, and interview with the TC 4/6/22, the laboratory director failed to evaluate the delegated responsibilities for 1 of 1 TC in 2019, 2020, 2021, and 2022. Findings: Review of personnel records revealed the TC's delegation of responsibility that was signed by the laboratory director on 6/13/19. The laboratory director delegated to the TC the responsibility for Quality Assurance, Quality Control, Policy & procedure manual, proficiency testing, initial training and lab competencies. Review of TC personnel records revealed there was no documentation of TC Competency assessments since the TC accepted the position in June of 2019. Interview with the TC at approximately 11:25 a.m. confirmed the laboratory director had not assessed her delegated responsibilities since she accepted the position in June of 2019.