Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0946272	10/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Carolina Medical Lab	1815 Back Creek Drive, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of coagulation records and interview with the Laboratory Operations Manager 10/4/22 - 10/6/22, the laboratory failed to retain the raw data used to calculate the reference (normal) range of prothrombin time (PT) when a new lot number of innovin, Lot #549717, was put into use on 1/12/20. Findings: Review of coagulation records revealed the laboratory had retained the "Executive Summary" for innovin Lot #549717, but failed to retain the raw data used to calculate the new reference (normal) range. Interview with the Laboratory Operations Manager on 10/6 /22 at approximately 11:00 am confirmed the laboratory failed to retain the raw data used to calculate the reference (normal) range for innovin, Lot #549717. He stated he was not employed when the new innovin was put into use and could not locate the raw data.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with the Microbiology general supervisor (GS) on 10/5/22, the microbiology procedure manual was not complete and current for the testing performed. Findings: Review of the laboratory's microbiology procedures revealed the procedures did not include all information needed for culture workup. For example: Review of the "Wound Culture" procedure revealed "... CULTURE WORKUP ... 4. Any organism has the potential to cause infection. However, the most common organisms associated with superficial wounds and abscesses are Staphylococcus aureus, Pseudomonas aeruginosa, members of the Enterobacteriaeceae, and beta-hemolytic streptococci. If any of these agents are found on a culture they generally should be worked up. 5. If the gram stain of a culture shows little to no white cells and epithelial cells and the culture is only growing normal skin flora quantify the growth and turn it out as normal skin flora and hold the culture for a week. 6. If there is only one organism found on the culture in great numbers work it up fully even if it appears to be normal skin flora. 7. Dipthroids are considered normal skin flora. Only work up if from sterile site or present in multiple cultures. 8. Yeast is part of normal skin flora but if 'feet' are present on the colony identify as presumptive Candida albicans. 9. If enteric gram-negative rods are found in small numbers, not predominant, or more than two species present turn out as mixed gastrointestinal microbiota. a. Unless the patient is diabetic, then work up to 3 gram negative rods, only minimally identifying the other enteric organisms present. ..." The procedure did not include step-by-step instructions for culture workup, including colony descriptions, subculture, identification methods, and antibiotic susceptibility testing. The procedure also included conflicting information regarding "normal skin flora", and failed to define terms such as "feet" and "minimally identifying". During interview at approximately 3:15 p.m., the Microbiology GS stated she was aware the microbiology procedures needed to be updated, but she had not had a chance to work on them.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, interview with staff, review of personnel records, and review of the Food and Drug Administration (FDA) website 10

	/6/22, the laboratory failed to follow manufacturer's instructions for performance of the Aptima SARS-Co-V-2 Assay performed on the Hologic Panther analyzer. Findings: 1. The laboratory failed to ensure that prior to testing patient specimens, 4 of 4 testing personnel (TP) had received the appropriate training and had demonstrated that they could perform all testing operations reliably to report accurate SARS-CoV-2 test results. Review of manufacturer's instructions for the Aptima SARS-Co-V-2 Assay performed on the Hologic Panther analyzer revealed on page 4 "... Warnings and Precautions ... B. Only personnel adequately trained on the use of this assay and in handling potentially infectious materials should perform these procedures. ..." On page 16, "Limitations A. Use of this assay is limited to personnel who are trained in the procedure. ..." On page 17, "Conditions of Authorization for Labs ... F. All laboratory personnel using the test must be appropriately trained ...". During interview at approximately 11:30 a.m., the Cytology general supervisor (GS) stated that SARS-C-V-2 patient testing began in July 2020. He stated that he and Technical supervisor (TS) #1 were trained in May 2020 by the manufacturer and they trained the other personnel. During interview at approximately 1:15 p.m., the Laboratory Operations Manager stated that only 4 TP perform SARS-CoV-2 testing on the Panther: TS #1, GS #2, GS #3, and the Cytology GS. Review of personnel records for TS #1, GS #2, GS #3, and the Cytology GS revealed there was no documentation of training for the Aptima SARS-Co-V-2 Assay performed on the Hologic Panther analyzer. 2. The laboratory failed to include relevant Fact Sheets with SARS-CoV-2 test results. Review of manufacturer's instructions for the Aptima SARS-Co-V-2 Assay performed on the Hologic Panther analyzer revealed on page 17 "... Conditions of Authorization for Labs ... A. Authorized laboratories usiung the Aptima SARS CoV-2 assay will include with result reports of the Aptima SARS CoV-2 assay, all authorized Fact Sheets. ...". Review of the FDA website revealed a "Fact Sheet for Healthcare Providers" and a "Fact Sheet for Patients". During interview at approximately 12:30 p.m., the Laboratory Operations Manager stated that the laboratory was unaware they were required to provide Fact Sheets with SARS-CoV-2 results.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of validation records and interview with the Microbiology general supervisor (GS) 10/6/22, the laboratory failed to establish performance specifications for the Periungal Infection PCR Panel and the Wound Infection PCR Panel performed on the Applied Biosystems QuantStudio 7flex analyzer. Findings: Review of validation records for the Applied Biosystems QuantStudio 7flex analyzer revealed the validation to establish performance specifications for the Periungal Infection PCR

	Panel and the Wound Infection PCR panel was performed for a laboratory that shares the same analyzer. There was no documentation of a separate validation of performance specifications. Interview with the Microbiology GS at approximately 3: 00 p.m. confirmed the laboratory did not establish performance specifications for the testing performed on the Applied Biosystems QuantStudio 7flex analyzer. She stated the analyzer is shared by another laboratory and she did not realize this laboratory would need to establish performance specifications also.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2020, 2021, and 2022 microbiology quality control records, and interview with the Microbiology general supervisor (GS) 10/5/22, the laboratory failed to document visual inspection of each new lot number/shipment of media. Review of the laboratory's "MEDIA HANDLING" procedure revealed "... PROCEDURE ... 5. Visually inspect plates, making sure that plates a. Have not been exposed to extreme temperatures b. Have not been frozen or melted c. Have no excess pitting or bubbles d. Are of an appropriate thickness (around 4mm in depth) e. Have not separated from the agar f. Are not cracked ... 8. After 72 hours fill out the sterility and quality sheet, noting whether or not the overall quality is acceptable. ..." Review of 2020, 2021, and 2022 microbiology quality control records revealed the laboratory had documented growth checks and sterility for each new lot number of media, but had not documented the visual inspection. During interview at approximately 3:05 p.m., the Microbiology GS stated the visual inspection was probably done but just not documented.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of 2021 and 2022 laboratory humidity logs and interview with the Laboratory Operations Manager 10/4/22 - 10/6/22, the laboratory failed to document

	and/or perform corrective action when humidity was not within the laboratory's acceptable range for 75 of 100 days reviewed in 2021 and 56 of 110 days reviewed in 2022. Findings: Review of laboratory humidity logs revealed an acceptable range of 25-85 percent (%). Review of 2021 and 2022 humidity logs revealed the logs were reviewed monthly and the humidity range recorded was less than 25% with no documentation of corrective action 75 of 100 days reviewed in 2021 and 56 of 110 days reviewed in 2022 for the following months: January 2021 - 22 of 23 days; February 2021 - 23 of 25 days; March 2021 - 17 of 27 days; April 2021 - 13 of 25 days; January 2022 - 21 of 22 days; February 2022 - 12 of 18 days; March 2022 - 15 of 29 days; April 2022 - 13 of 25 days. Interview with the Laboratory Operations Manager 10/4/22 at approximately 3:00 p.m. confirmed the laboratory failed to document and/or perform corrective action when humidity recordings were not within the laboratory's acceptable limits. He also stated he would review the acceptable range to ensure the range was correct for the testing performed.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2020, 2021, and 2022 American Proficiency Institute (API) proficiency testing records 10/4/22, the laboratory director failed to ensure evaluation of all ungraded and unacceptable proficiency testing results to identify any problems requiring corrective action. Findings: Review of the laboratory's "QUALITY MANAGEMENT (QM) PROGRAM policy revealed "... Proficiency Testing: ... Follow up & Investigation: 1. Comparative evaluation of results will be reviewed by the LOM. All unacceptable results must be investigated. Print the Performance Review and Corrective Action Documentation form from the online website. Check for clerical errors, proper handling of specimen (was the tested within stability, sample diluted according to directions, calibration & maintenance up-to-date, QC within acceptable limits, reagent stability acceptable). List explanation of unacceptable results and if patient results are affected. Describe the corrective action taken to resolve the immediate issue ... and preventative action so that this issue does not reoccur. ... 4. The results and if necessary, investigative reports will be approved by the LD. 5. File all completed results on site for two years in PT binders. Ungraded Proficiency Testing (PT) Challenges: ... For all ungraded results on a PT challenge, document the reason /explanation for the occurrence. PT challenges that were intended to be graded but were not graded for whatever reason, will be managed the same way graded challenges are handled. ... Failures are investigated the same way graded results are managed. ..." Review of 2020, 2021, and 2022 API proficiency testing results revealed the laboratory failed to document evaluation of all ungraded and unacceptable proficiency testing results. Examples: 1. 2021 Microbiology 3rd event - no evaluation of unacceptable Gram stain result for sample GS-13, no evaluation of ungraded urine culture MIC results for sample UR-11; 3. 2021 Hematology /Coagulation 3rd event - no evaluation of ungraded results for 7/7 advanced blood cell ID samples (ABI-15, 16, 17, 18, 19, 20, 21); 4. 2022 Microbiology 2nd event - no evaluation of ungraded urine culture MIC results for sample UR-06.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of coagulation records, review of patient test report and interview with the Laboratory Operations Manager 10/4/22 - 10 /6/22, the laboratory director failed to ensure the reference (normal) range for prothrombin time (PT) was updated in the laboratory information system (LIS) when a new lot number of innovin was put into use. Approximately 7376 patients were tested from 1/12/20 to 8/9/21 when the reference (normal) range was incorrect. Findings: Review of laboratory procedure "COAGULATION LOT CONVERSION" states "NOTE: all reference range changes MUST be changed in the laboratory information system (LIS) before reporting with new ranges." Review of coagulation records revealed a new lot of innovin, Lot #549717, was put into use on 1/12/20. Data summary for Lot #549717 revealed a new PT reference range of 9.7-12.6. Review of the coagulation records also revealed Lot #549717 was in use until 8/9/21. Review of patient test report, MRN 2002458 dated 1/28/20, revealed a reference (normal) range of 9.9-11.8. During interview on 10/6/22 at approximately 11:00 am, the Laboratory Operations Manager confirmed the new reference (normal) range for innovin Lot #549717 was not updated in the LIS. He also confirmed 7376 patients were tested from 1/12/20 to 8/9/21.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions (MI), review of patient test reports and interview with the laboratory operations manager 10/4/22-10/6/22, the laboratory director failed to ensure the test reports for Prostate-specific Antigen (PSA) and Alpha-fetoprotein (AFP) included the methodology of the assays. Findings: Review of MI for PSA revealed "WARNING ...The concentration of PSA in a given specimen determined from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the PSA assay used. Values obtained with different assay methods cannot be used interchangeably." Review of MI for AFP revealed "CAUTION ... The concentration of AFP in a given specimen determined from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the AFP assay used. Values obtained with different assay methods cannot be used interchangeably." Review of patient test reports, MRN 39378 dated 1/24/22 and MRN 7007 dated 2/2/22, revealed the test reports failed to include the methodology of the PSA and AFP assays. Interview with the Laboratory Operations Manager 10/6/22 at approximately 3:00 p.m. confirmed the test reports did not include the methodology of the PSA and AFP assays.