Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0694472	05/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Carolinas Center For Surgery	306 Medical Park Court, Morehead City, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of 2021, 2022 and 2023 proficiency testing (PT) records, lack of documentation and testing personnel (TP) interview 5/24/23, the laboratory failed to ensure TP whom performed the PT testing and the laboratory director (LD) signed attestation statements for 13 of 13 PT events reviewed. Findings: Review of 2021, 2022 and 2023 PT records for Hematology and Microbiology revealed no documentation of attestation statements for 13 of 13 PT events in which the laboratory participated. Interview with TP #2 at approximately 11:20 a.m. confirmed TP whom participated in PT and the LD did not sign attestation statements for 13 of 13 PT events.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of 2022 and 2023 microbiology PT records and TP interview 5/24 /23, the laboratory failed to ensure all unacceptable PT results were evaluated to ensure corrective action was taken if necessary. Findings: Review of 2022 and 2023 microbiology PT records revealed the LD had signed their review of the PT events.

	The LD's review failed to include an evaluation of the following unacceptable PT results: First microbiology event of 2022 - Sample UR-10. Second microbiology event of 2023 - Sample UR-03. Interview with TP #2 at approximately 11:20 a.m. confirmed there was no documentation the unacceptable PT results were evaluated.
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 Uricult quality control (QC) records and TP interview 5/24/23, the laboratory failed to perform QC on the Uricult media that included a gram-positive bacteria to ensure the media was able to support the growth of both gram-negative and gram-positive bacteria. Findings: Review of Uricult QC records revealed the laboratory performed QC utilizing a gram-negative bacteria, Escherichia coli. There was no documentation of Uricult QC performed utilizing a gram-positive bacteria. Interview with TP #2 at approximately 11:30 a.m. confirmed the laboratory was performing QC on the Uricult media utilizing a gram-negative bacteria, Escherichia coli.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and TP interview 5/24/23, the LD failed to ensure quality assessment programs were established to monitor and access the quality of laboratory services provided. Findings: Review of laboratory's policies and procedures revealed no documentation of a quality assessment program to monitor and access the quality of laboratory services provided. Interview with TP #2 at approximately 11:30 a.m. confirmed the laboratory does not have a quality assessment program in place.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.

	1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of laboratory personnel records 5/24/23 and the deficiency cited at D6065, the laboratory failed to verify that 1 of 4 TP met the minimum education requirements for performing moderate complexity testing. Findings: See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and TP interview 5/24/23, the laboratory failed to verify that 1 of 4 TP met the minimum education requirements for performing moderate complexity testing. Findings: Review of laboratory personnel records revealed TP #4 education documentation consisted of certifications for Nursing Aide and Radiological Technician. Interview with TP #2 at approximately 11: 30 a.m. confirmed TP #4 education documentation consisted of certifications for Nursing Aide and Radiological Technician.