Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0246750	05/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Carolina Oncology Specialists, Pa	2406 Century Place Se, Hickory, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and interview with testing personnel (TP) #1 on 5/28/25, the laboratory failed to establish policies and procedures for evaluating the competency of the technical consultant (TC) and the clinical consultants (CC). Findings: Review of the "Laboratory Quality Assurance Policy" revealed "... I. TESTING PERSONNEL ... C. Laboratory personnel will be evaluated annually by the Laboratory Director ... or the Technical Supervisor ... , and will have competency testing which will include direct observation of test being performed, running controls on analyzer, and observation of critical thinking regarding results produced. ..." The policy did not include a description of the method for evaluating TC and CC competency. Review of personnel records for the TC and the 4 CCs revealed no documentation of competency evaluation. During interview at approximately 10:20 a.m., TP #1 verified that they did not have a policy for evaluating TC and CC competency.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to

	verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the TOSOH AIA 900 reagent logs, review of instructions for use (IFU) for Ferritin (FER) and Carcinoembryonic Antigen (CEA) test cups and calibrator sets, lack of documentation, and interview with TP #1 on 5/28/25, the laboratory failed to perform semiannual calibration verification using at least 3 values (zero, mid-point, and upper level), for Ferritin and Carcinoembryonic Antigen in 2023 and 2024. Findings: Review of the TOSOH AIA 900 reagent logs revealed both Ferritin and CEA test cups were periodically purchased for use since 11/23/23. Review of test cup and calibrator set IFUs for Ferritin and CEA revealed the following: 1. The ST AIA-PACK FER test cup IFU states, "The following materials are required to perform analysis using the ST AIA-PACK FER on the Tosoh AIA System analyzers....AIA-PACK FER CALIBRATOR SET....." The IFU for AIA-PACK FER CALIBRATOR SET reveals two assigned ferritin levels to build a standard curve, including: a. 0 nanograms per milliliter (ng/ml) b. 500 nanograms per milliliter (ng/ml) 2. The ST AIA-PACK CEA test cup IFU states, "The following materials are required to perform analysis using the ST AIA-PACK CEA on the Tosoh AIA System analyzers....AIA-PACK CEA CALIBRATOR SET....." The IFU for AIA-PACK CEA CALIBRATOR SET reveals two assigned CEA levels to build a standard curve, including: a. 0 nanograms per milliliter (ng/ml) b. 50 nanograms per milliliter (ng/ml) Review of the TOSOH AIA 900 calibration records revealed no record of calibration verification in 2023 or 2024. During an interview at approximately 2:30 p.m., TP #1 confirmed there were no calibration verification documents for review. She stated the oversight was noted during retraining conducted by a Tosoh representative in 2025.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2024 and 2025 MLE (Medical Laboratory Evaluation) proficiency testing records 5/28/25, the laboratory director failed to document review of 4 of 4 proficiency testing events to evaluate the laboratory's performance and identify any problems requiring corrective action. Findings: Review of the "Laboratory Quality Assurance Policy" revealed "... V. PROFICIENCY TESTING ... B. The proficiency testing results are reviewed and

	signed by the Laboratory Director and Technical Consultant. Proficiency testing results also be reviewed with the entire laboratory staff. Any unacceptable results will be discussed with corrective action(s) taken if needed (i.e. retraining, etc.). The discussions, findings, and corrective actions(s) will be documented. ..." Review of 2024 and 2025 MLE proficiency testing records revealed the graded results for the 2024 M1, M2, and M3 test events and the 2025 M1 test event had not been signed and dated by the laboratory director to document review.