Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2010923	06/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Southern Oncology Specialists	9930 Kincey Avenue Suite 165, Huntersville, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based upon observation, review of manufacturer's instructions, the absence of records, and interview with TC (technical consultant) #1 on 6/19/23, the laboratory failed to monitor and document the temperature of a freezer used to store calibration materials for the Beckman Access 2 instrument. Findings: During a tour of the laboratory at approximately 1:50 p.m., the surveyor observed Beckman Access Folate and Vitamin D calibration materials in the freezer compartment above the refrigerator. Manufacturer's instructions for the storage of Folate calibration material require upright frozen storage below -20 degrees Celsius. Manufacturer's instructions for the storage of Vitamin D calibration material require upright frozen storage between -15 and -30 degrees Celsius. There was no documentation of the freezer's temperatures for the years of 2021, 2022 or 2023. During an interview at approximately 1:55 p.m., TC #1 confirmed that the temperature of the freezer compartment is not monitored. She stated the laboratory does not record the freezer temperature because no patient samples are stored inside.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based upon observation, review of the manufacturer's instructions, and interview with TC (technical consultant) #1 on 6/19/23, the laboratory failed to discard quality control material after the open expiration date was exceeded. Findings: During a tour of the laboratory at approximately 1:50 p.m., the surveyor observed Biorad Liquicheck immunoassay premium controls lot #89313 marked with an in-use date of 6/7/23 in the refrigerator, available for use. Review of the product insert for the Biorad Liquicheck immunoassay premium controls revealed the "Storage and Stability" section specified a 4 day open expiration date for the analyte folate and a 9 day open expiration date for the analyte Vitamin D after the control material is thawed and opened. During an interview at approximately 2:35 p.m., TC #1 confirmed that Biorad Liquicheck immunoassay premium controls are not discarded in accordance with the manufacturer's requirements and that she has not noticed any issues with the quality control values. In 2022, the laboratory reported approximately 1,764 patient folate test results and approximately 1,843 patient Vitamin D test results.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of performance verification records and interview with TC (technical consultant) #1 on 6/19/23, the laboratory failed to define the criteria of acceptability used to verify the performance of the AU480, the Access 2, and the Sysmex XN analyzers when the facility changed locations in July of 2021. Findings: Review of performance verification records for the AU480, the Access 2, and the Sysmex XN analyzers revealed the laboratory had performed a split-sample analysis using previously tested patient samples for each test performed on the 3 analyzers. The records failed to include the criteria used to determine the acceptability of the split-sample analysis. Interview with TC #1 at approximately 3:00 p.m. confirmed the performance verification records failed to include the criteria used by the laboratory to determine the acceptability of the split-sample analysis.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of 2020, 2021, 2022, and 2023 maintenance records, the absence of records, and interview with TC (technical consultant) #1 on 6/19/2023, the laboratory failed to perform and document all monthly maintenance specified by the manufacturer for the AU480 Chemistry analyzer for 4 of 12 months in 2021 (July, August, November, and December). Findings: Review of the AU480 User Guide, Chapter 8, maintenance schedule 8-61, revealed 4 monthly maintenance requirements listed in the following order: Clean the sample and reagent probe wash wells. Clean the Mix bar Wash Wells. Clean the wash Nozzle unit, and Check the tube mounting joints. Clean the Deionized Water Tank, DI and Sample probe Filters. Review of 2020, 2021, 2022, and 2023 maintenance records revealed: 1. The laboratory failed to perform and document 2 of 4 monthly maintenance requirements for 2 months, July and August 2021. Monthly maintenance items not documented: Clean the wash Nozzle unit, and Check the tube mounting joints. Clean the Deionized Water Tank, DI and Sample probe Filters. 2. The laboratory failed to perform and document 4 of 4 monthly maintenance requirements for 2 months, November and December 2021. During an interview at approximately 2: 04 p.m., TC #1 confirmed monthly maintenance was not documented as required on the maintenance logs. TP #1 was unable to print maintenance documentation from the instrument for July, August, November, and December 2021.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of performance verification records and interview with TC (technical consultant) #1 on 6/19/23, the laboratory director failed to ensure performance verifications for the AU480, the Access 2, and the Sysmex XN analyzers were acceptable before patient testing resumed in July of 2021 after the instruments were moved. Review of performance verification records for the AU480, the Access 2, and the Sysmex XN analyzers revealed the laboratory had performed a split-sample analysis using previously tested patient samples for each test performed on the 3 analyzers. The records did not include documentation of the laboratory director's review and approval. Interview with TC #1 at approximately 3:00 p.m. confirmed the performance verification records failed to include documentation of the laboratory director's review and approval.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) 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 and review of 2 random patient test reports (Patient #10820, Patient #21450) on 6/19/23, the laboratory director failed to ensure patient test reports for the Prostate Specific Antigen (PSA) and cancer antigen 125 (CA-125) included the identity of the assay used. Findings: 1. Review of manufacturer's instructions for the PSA assay revealed "The results reported by the laboratory to the physician must include the identity of the PSA assay used." Review of a random patient test report for PSA (Patient #10820, Report Date: 6/15/23) revealed the patient test report failed to include the identity of the assay used. 2. Review of manufacturer's instructions for the CA-125 assay revealed "The results reported by the laboratory to the physician must include the identity of the CA-125 assay used." Review of a random patient test report for CA-125 (Patient #21450, Report Date: 5/24/23) revealed the patient test report failed to include the identity of the assay used.