Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2150458	11/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Southern Oncology Specialists	268 Gillman Road Suite A, Denver, 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 2018, 2019 and 2020 hematology QC (quality control) and calibration records and the absence of documentation 11/16/20, the laboratory failed to retain all required hematology QC and Calibrator assay sheets in 2019 and 2020. Findings: Review of 2018, 2019 and 2020 CELL-DYN Emerald QC and calibration records revealed the laboratory failed to retain copies of the CELL-DYN Plus control assay sheets and CELL-DYN Plus Calibrator assay sheets for the following lot numbers: 1. Control lot # 8295, expiration date 2/8/19; 2. Control lot # 9098, expiration date 7/26/19; 3. Control lot # 9266, expiration date 1/10/20; 4. Control lot # 0153, expiration date 9/18/20; 5. Calibrator lot # 9350C, expiration date 2/3/20- in use for calibration performed on 2/3/20.
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 Orchard LIS(laboratory information system) online operator's manual, absence of validation records for the Orchard LIS, and interview with the TC (Technical Consultant) 11/16/20, the laboratory failed to determine if the performance of the Orchard LIS was acceptable before performing patient testing. Findings: Review of the Orchard LIS online operator's manual and review of laboratory records revealed no documentation the laboratory had validated the performance of the Orchard LIS. Interview with the TC at approximately 3:00p.m. confirmed there was no documentation the laboratory had validated the performance of the Orchard LIS before performing patient testing. She stated the Orchard LIS team may have the documentation on file and she would contact them.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory's procedures, review of 2018, 2019, and 2020 CELL-DYN Emerald hematology analyzer calibration records, and interview with TC 11/16/20, the laboratory failed to perform calibration verification at least once every 6 months and failed to document quality control required after the calibration was performed. Findings: The laboratory's CELL-DYN Emerald procedure and the CELL-DYN Emerald Operator's Guide states under Calibration, "...Calibration should be confirmed on a regular basis according to your laboratory's protocol....Criteria should also be established for calibration verification. Calibration verification criteria include: When indicated by Quality Control data....After major maintenance and service procedures....At least every six months.... As directed by the regulatory agencies governing the laboratory." The CELL-DYN Emerald procedure states under Quality Control, " Abbott recommends you run controls: ....After calibration (confirmatory step)....." a. Review of calibration records revealed calibration verification was performed on the CELL-DYN Emerald on 6/1/18, over 7 months later on 1/23/19(day of service) and 2/8/19, 12 months later on 2/3/20, and 7 months later on 9/18/20. b. Review of calibration records revealed the laboratory failed to document testing quality control after calibration to confirm acceptability of the CELL-DYN Emerald on 6/1/18, 1/23/19, 2/8/19, and 2/3/20. Interview with TC at approximately 2:30p.m. confirmed calibration verifications were performed past the 6-month time frame and the laboratory failed to document quality control as the calibration confirmatory step.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)

	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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of CMS(Centers for Medicare and Medicaid Services) Casper Report 155D, review of 2018, 2019, and 2020 PT(Proficiency testing) records, and interview with TC(Technical Consultant) 11/16/20, the laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for the 1st and 2nd Hematology events in 2019. Findings: Review of CMS Casper Report revealed PT scores for 2018 3rd event and 2019 3rd event, but no scores for the 2019 1st or 2nd event. Review of laboratory's PT records revealed no documentation for the 2019 1st and 2nd hematology events. Interview with the TC at approximately 1 p.m. confirmed the laboratory failed to enroll on time for 2019. She stated the laboratory should have enrolled around December 2018 but since the facility was only operating on intermittent days, the PT enrollment was overlooked. She confirmed the laboratory did not enroll in PT for 2019 until 7/23/19.
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 2018, 2019, and 2020 hematology calibration records, review of 2018,2019 and 2020 PT(proficiency testing) records and review of 2018, 2019, and 2020 QA(quality assurance) records and interview with the Laboratory Director 11/16 /20, the laboratory director failed to ensure the laboratory's QA program was able to identify and correct problems as they occurred. Findings: Review of 2018, 2019, and 2020 QA records revealed Quality Assurance forms were completed monthly from June 2018 through December 2019. Review of the monthly forms revealed the QA program failed to identify and correct problems in the laboratory for calibration verification and proficiency testing enrollment(See D5439 and D6015). For example: a. On the December 2018 QA form, the response of "NO" was given for question #2 "Was calibration due this month? if so, are there any issues with calibration to report?" There was no documentation to address that calibration was due in December 2018 but not performed until January 2019. b. On the June 2019 QA form, the response of "NO" was given for question #5 "Was proficiency due and/or performed this month? If so, are there any issues or concerns to report." There was no documentation to address that proficiency testing had not been performed in 2019 and was not ordered until July 2019. Review of QA records revealed the only documentation of QA in 2020 was the Technical Consultant's report completed in

	September 2020. During exit interview at approximately 3:30 p.m., the Laboratory director confirmed the laboratory's QA program failed to identify and correct problems as they occurred.