Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2010923	04/10/2018
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
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 laboratory policy, review of 2016 and 2017 American Proficiency Institute (API) proficiency testing (PT) records and review of College of American Pathologists (CAP) PT records 04/10/18, the laboratory director failed to sign attestation statements for all laboratory PT testing performed. Review of laboratory's quality assessment policy, "Proficiency Test Assessment", revealed the following statement, "2. Completeness (Including directors signature and testing personnel on the attestation statement." Review of 2016 and 2017 API and CAP PT records revealed the laboratory director failed to sign attestation statements for the following PT events: 1. API-2016 Chemistry Group 2 - 3rd Event 2. Y-A 2016 CAP Ligand - Special - 1st Event
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 laboratory policy and review of 2016 and 2017 API PT records 04 /10/18, the laboratory failed to review all results obtained on the PT performed. Review of laboratory's quality assessment policy, "Proficiency Test Assessment",

	revealed the following statement, "The director will sign and date the PT results and indicate his review." Review of 2016 and 2017 API PT records revealed the director did not sign or date the following PT events to indicate the laboratory's review of results obtained on the PT performed. 1. API-2016 Immunology/Immunohematology - 1st Event 2. API-2016 Immunology/Immunohematology - 2nd Event 3. API-2016 Immunology/Immunohematology - 3rd Event 4. API-2016 Hematology/Coagulation - 2nd Event 5. API-2017 Chemistry - Core - 1st Event 6. API-2017 Hematology /Coagulation - 2nd Event 7. API-2017 Immunology/Immunohematology - 1st Event 8. API-2017 Immunology/Immunohematology - 2nd Event 9. API-2017 Immunology /Immunohematology - 3rd Event
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review 2016 and 2017 API PT records, and interview with TP (testing personnel) 04/01/18, the laboratory's quality assessment failed to include a review of the effectiveness of corrective actions taken to resolve PT failures for the analyte, CA19-9 (Cancer Antigen 19-9). Review of laboratory's quality assessment policy, "Proficiency Test Assessment", revealed the following statement, "All PT results will be reviewed by the director for the following:.....4. Effectiveness of corrective actions taken in the event of any unacceptable or unsuccessful PT result." Review of 2016 and 2017 API PT records for CA19-9 revealed the laboratory had unsuccessful PT performance in 4 out of 5 events. Review of corrective action for the unsuccessful PT performances revealed the corrective action taken was a review of quality controls and/or a retesting of PT samples. There was no documentation of a review of the effectiveness of the corrective actions taken to resolve the PT failures. Findings: 1. API-2016 Chemistry Group 2 - 1st Event, the laboratory received a score of 50% for CA19-9, corrective action states, "The original samples for tumor marker test CA19-9 were rerun, and all CA19-9's are w/in range." 2. API-2016 Chemistry Group 2 - 2nd Event, the laboratory received a score of 50% for CA19-9, corrective action states, "19-9's for samples TM-03 and TM-04 removed from freezer and re-rerun. Both samples ran in duplicate and both w/in range. Controls w/in range on original date samples were run and on 11/05/16 when rept'd." 3. API-2016 Chemistry Group 2 - 3rd Event, the laboratory received a score of 0% for CA19-9, corrective action states, "Repeated TSH on CH12, UIBC on CH14 and Ca19-9 on samples TM05 and TM06. All results w/in acceptable range.....All controls were w/in range on day of initial testing (11-30-16) and all controls w/in range on date of rpt testing (01-18-17)." 4. API-2017 Chemistry-Miscellaneous - 2nd Event, the laboratory received a score of 67% for CA19-9, corrective action states, "CA19-9 TM-04 expected result 12.0 - 17.7. We entered 18.0 which is slightly (high). Rpt on original sample (frozen) gave result 12.4. This is w/in expected range." During exit interview at approximately 530 PM, TP #1 confirmed the laboratory's quality assessment failed to include a review of the effectiveness of corrective actions taken to resolve PT failures for the analyte, CA19-9.

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 TP (testing personnel) 4/10/18, the laboratory's policies and procedures were not complete and current for the testing performed. Findings: 1. The Flow Cytometry procedure manual did not include the laboratory's current quality control procedure. The "QUALITY CONTROL AND QUALITY IMPROVEMENT" procedure states "... QUALITY CONTROL Daily QC A. A reference control, Streck CD Chex Plus, is set up and run weekly ..." During interview at approximately 4:45 p.m., TP #2 stated that they run two Streck controls each day of testing. She stated the procedure needs to be updated. 2. The "SPECIMEN COLLECTION, HANDLING AND STORAGE" procedure states "... C. CANCELLATION Any cancelled case MUST be reviewed and signed by a Pathologist. Client Service will notify the clients. ... H. ACCESSIONING OF FLOW SPECIMENS. 1. Specimens are accessioned in AP Easy by Front Office... During interview at approximately 4:45 p.m., TP #2 confirmed that the laboratory does not have a pathologist and does not use AP Easy. She stated that the procedure was not written by the laboratory but was provided by an outside laboratory. 3. The "Sysmex XN-1000 / XN-2000 Automated Hematology Analyzers CLSI Procedure" had not been customized by the laboratory to include laboratory-specific information. For example, on page 17, the procedure states "... Follow laboratory protocol for troubleshooting Quality Control results exceeding the upper or lower limit of acceptability. Complete this section with your laboratory's QC action plan for out of range commercial control products and X-barM. ..." 4. The laboratory's "QUALITY CONTROL" policy had not been updated to reflect current equipment. It states "MECHANICAL EQUIPMENT Cell-Dyn Emerald machine is used at the office. ... OPERATIONS ... Daily start-up procedures are performed on the Cell-Dyn Emerald. ..." The laboratory uses a Sysmex XN hematology analyzer. This deficiency was cited on the previous survey 1/7/16.