Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0714409	02/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Oncology Associates	30160 Orchard Lk Rd Suite 100, Farmington Hills, MI	

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 record review and interview with testing personnel #2 and #3 (TP2 and TP3), the laboratory director and TP failed to attest to the routine integration of the hematology proficiency testing (PT) samples into the patient workload for two (2nd events in 2017 and 2018) of five events reviewed. Findings include: 1. Review of the PT records revealed the attestation statement sheet was not signed as follows: a. 2nd event 2017 - not signed by the laboratory director b. 2nd event 2018 - not signed by the TP 2. During the interview on February 25, 2019 at 11:35 AM, TP2 and TP3 confirmed the attestation statement sheet was not signed.
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: Eye Wash . Based on record review and interview with testing personnel #2 and #3 (TP2 and TP3), the laboratory failed to follow written policy for two (February 2017 to February 2019) of two years reviewed. Findings include: 1. Review of the "CLIA Compliance Manual" under the red tab labeled "Eyewash" is a "Weekly Eye Wash Station Inspection Checklist and Log". 2. Record review of the "Weekly Eye Wash Station Inspection Checklist and Log" revealed the laboratory documented the inspections on a monthly basis for two years. 3. During the interview on February 25, 2019 at approximately 3:00 PM, TP2 stated she thought the inspections were performed and documented monthly. Quality Control . Based on procedure review, record review, and interview with testing personnel #2 and #3 (TP2 and TP3), the laboratory failed to follow the quality control procedures for four (#3, #5, #9, and #10) of ten patient charts audited. Findings include: 1. Quality control (QC) procedure review stated "All control results must be in expected ranges before patient test results are reported". "The laboratory is to test three different levels (low, normal, and high) each day of testing." 2. Record review of the audited charts revealed the laboratory turned out patient results when control material was not within expected ranges as follows: a. #3 (9/20/18) - high control, low flag on the red blood cell (RBC) and hemoglobin results b. #5 (3/20/18) - normal and high control, high flag on the platelet count c. #9 (5/23/17) - high control, low flag on the RBC d. #10 (3/30/17) - high control, low flag on the RBC and hematocrit; high flag on the mean corpuscular hemoglobin concentration 3. During the interview on February 25, 2019 at approximately 3:00 PM, TP3 confirmed that all controls were not within expected ranges before reporting out patient results. 4. The laboratory reported out the following number of patients on the four days that controls were not within expected ranges: a. 9/20/18 - ten patients b. 3/20/18 - five patients c. 5/23/17 - five patients d. 3 /30/17 - eight patients
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: . Based on observation, procedure review, and interview with testing personnel #2 and #3 (TP2 and TP3), the laboratory failed to establish, perform, and document

	thermometer calibrations. Findings include: 1. On February 25, 2019 at 11:18 during a tour of the laboratory, the surveyor observed a Fisher Scientific thermometer/humidity thermometer in use with an expiration date of March 17, 2011. 2. Procedure review of the "CLIA Compliance Manual" in the "Safety and Environment" section under the title "The Testing Environment" revealed the laboratory did not have a policy and procedure for the calibration of the thermometers. 3. During the interview on February 25, 2019 at 3:00 PM, TP2 and TP3 confirmed no procedure was developed or implemented for the calibration of thermometers.
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 surveyor review of calibration records and interview with testing personnel #2 and #3 (TP2 and TP3), the laboratory failed to follow and document the calibration procedures according to the manufacturers' instructions for one of two yearly calibrations. Findings include: 1. Review of the calibration records revealed the laboratory did not have any documentation to show the calibrations were performed for one of the two yearly calibrations in 2018. 2. The manufacturer's instructions require calibration every six months. 3. During the interview on February 25, 2019 at 10:23 AM, TP2 and TP3 confirmed the laboratory had not performed the calibration every six months in 2018. ***Repeat Deficiency from the September 8, 2016 survey***
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #2 and #3 (TP2 and TP3), the laboratory director failed to ensure the final proficiency testing (PT) reports were reviewed by the appropriate TP for three of five events reviewed. Findings include: 1. Record review of the final PT reports revealed the appropriate TP did not

	review the reports when returned to the laboratory as follows: a. 2017 - 2nd and 3rd events b. 2018 - 1st event 2. During the interview on February 25, 2019 at approximately 3:00 PM, TP2 and TP3 confirmed the TP did not review and evaluate their performance on the PT events.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #2 and #3 (TP2 and TP3), the technical consultant failed to evaluate three (#1 - #3) of three TP performing the moderately complex hematology testing at least annually after the first year. Findings include: 1. Record review of the competency assessments revealed the laboratory did not have any documentation to show the competencies had been performed and documented for three TP in 2017 and 2018. 2. During the interview on February 25, 2019, TP2 and TP3 confirmed competency assessments had not been performed and documented in 2017 and 2018.