Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0246750	10/14/2019
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
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 2017, 2018, and 2019 Abbott Cell-Dyn Ruby Hematology quality control and calibration records, and interview with testing personnel(TP) 10/14/19, the laboratory failed to retain all required records for at least two years. Findings: The laboratory performs complete blood counts with differential(CBCD) testing on 2 Cell-Dyn Ruby Hematology analyzers. Hematology analyzer #1 is located in the main lab. Hematology analyzer #2 is located in the treatment room. 1. Review of the Hematology quality control records revealed the laboratory failed to retain quality control assay sheets listing acceptable ranges for the following lot numbers: a. Cell-Dyn 26 Plus Control- lot #7254, in use 9/28/17- 11/24/17; b. Cell-Dyn 26 Plus Control-lot #8113, in use 5/11/18-7/6/18. 2. Review of Hematology calibration records revealed the laboratory failed to retain calibration assay sheets for the following lot number: a. HemCal Plus Calibrator- lot CD8141, used for calibrations performed on 6/29/18. During interview at approximately 2:30 p.m., TP#6 confirmed the records were not available.
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 procedure manual review, observation, and interview with TP 10/14/19, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. The laboratory's procedure manual failed to include a procedure describing the course of action to take if the Ankhos Oncology EMR (electronic medical record) became inoperable. During interview at approximately 4:30 p.m., TP #6 stated there should be a policy available for computer downtime, but she was unable to locate the policy in the procedure manual at time of interview. This deficiency was previously cited at 8/27/15 survey. 2. The laboratory's procedure manual failed to include Hematology reference intervals(normal values) for the CBCD test. During interview at approximately 4:30 p.m., TP#6 confirmed the reference intervals were not available. 3. The laboratory's procedure manual included 2 procedures "Urine Microscopy" and "Urinalysis" for the reporting of urine microscopy parameters. For example, in the "Urine Microscopy" Procedure , bacteria and mucus are reported as few, moderate, or many. In the "Urinalysis" procedure, microscopic examination for bacteria and mucus are reported as 1+, 2+, 3+, or 4+. 4. The laboratory uses HealthLink QuickLink III staining reagent for the performance of manual differential staining, as observed by the surveyor during tour of the laboratory at approximately 12:45 p.m. The laboratory's procedure "White Blood Cell Manual Differential Procedure" states, "The blood film is stained using Hema 3 Stain Set... refer to the package insert included in the Procedure manual for staining procedure and principle." The laboratory's procedure failed to include a process for detection of inadequately prepared slides. During interview at approximately 12:45 p.m, TP#6 confirmed the laboratory did not have a procedure to check the quality of blood smears each day slides are prepared. She also confirmed a package insert for the QuickLink III was not available.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 procedures, review of 2017, 2018, and 2019 Cell-Dyn Ruby hematology analyzers calibration records, and interview with TP 10/14/19, the laboratory failed to perform calibration at least once every 6 months and failed to document the quality control required after calibration was performed. Findings: The laboratory's Calibrations procedure states, "...the CELL-DYN Ruby hematology analyzer is calibrated every six months or sooner if indicated by Technical Support.... Controls will be performed following calibrations." a. Calibration records revealed the Hematology analyzers were calibrated 11/29/17(Ruby #1) and 11/24/17(Ruby #2), 7 months later on 6/29/18, 8 months later on 2/15/19, and 7 months later on 9/27/19. Interview with TP#6 confirmed calibrations were performed past the 6-month time frame. This deficiency was previously cited at 8/27/15 survey. b. The laboratory failed to document testing three levels of quality control material after calibration to verify acceptability of the Ruby #2 on 11/24/17 and 6/29/18.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records, absence of documentation, and interview with TP 10/14/19, the Laboratory director (LD) failed to ensure 2 of 12 TP received appropriate training and could demonstrate performance of CBCD testing on the Hematology analyzers prior to reporting patient test results. Findings: Review of personnel records for TP#10 and TP#11 revealed there was no documentation of initial training available for the Cell-Dyn Ruby analyzer. During interview at approximately 2:30p.m., TP#6 stated TP#10 was hired in June 2018 and TP#11 was hired in September 2017. She also confirmed there was no documentation of initial training for TP#10 and TP#11. Review of records revealed TP#10 had re-training documented on 6/18/19 following her competency assessment.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)

	The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of 2018 and 2019 personnel records, absence of documentation and interview with TP 10/14/19, the LD failed to assess the competency for the Technical Supervisor (TS) for designated duties and testing performed. Findings: The "Competency Evaluation Attestation Statement" dated 10/6/17 revealed the TS was designated by the LD to carry out evaluations. During interview at approximately 2:30 p.m., TP#6 confirmed the TS also performs abnormal blood smear review. Review of personnel records revealed there was no documentation of competency for the TS for her designated duties. Review also revealed no documentation of competency for the testing performed by the TS.