Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2044957	09/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Regional Medical Oncology Center	2624 Ortho Drive, Wilson, 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
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 laboratory quality assessment policy, review of quality assessment records and testing personnel (TP) interview 9/12/18, the laboratory director failed to ensure that all aspects of the laboratory's established quality assessment program were maintained from time of last survey, 8/25/16, until August 2018; a period of approximately 24 months. Review of laboratory's quality assessment policy revealed the laboratory director had established a quality assessment program that included a "Quality Assurance Monitoring Schedule" and "Monthly QA reviews"..."to include .... QC review, including CQAP report, Maintenance logs review, Temp and humidity level logs review, Patient test management review (5 records/month) and Complaints /problems/corrective actions review." Review of laboratory's quality assessment records revealed TP #2, who began employment in January of 2018, completed the "patient test management review" aspect of the established quality assessment program, for each month beginning with September 2017 until August 2018. Review of laboratory's quality assessment records revealed "Monthly QA reviews" were completed for September 2018. There was no documentation of additional "Monthly QA reviews", as established in the laboratory's quality assessment program from time of last survey, 8/25/16, until August 2018; a period of approximately 24 months. Interview with TP #2, at approximately 1:00 p.m., confirmed the "Monthly QA reviews" were not maintained as established in the laboratory's quality assessment

	program. She stated they were not aware of the QA reviews required until we began preparing for the CLIA survey.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of laboratory policies, laboratory personnel records, review of testing personnel (TP) competency records and technical consultant (TC) interview 09/12/18, the technical consultant (laboratory director) failed to evaluate the competency of 1 of 1 testing personnel in 2016 and 2 of 2 testing personnel in 2017. The laboratory director served as the technical consultant for the laboratory until January 2018. The current technical consultant responsible for reviewing TP competency has completed the competency reviews for 4 of 4 testing personnel in 2018. Review of laboratory policy "Personnel Training & Competency Assessment" revealed "#2. All employees performing laboratory testing will demonstrate competency in every test/procedure performed. This competency will be assessed by the Technical Consultant or the Lab Director...a. All new employees will have competency assessment done every 6 months for one year. b. After the first year of employment, competency assessment will be done and documented annually." Review of laboratory personnel records and TP competency records revealed the TC (laboratory director) failed to evaluate the competency of TP #2 in 2016. Review of laboratory personnel records and TP competency records revealed the TC (laboratory director) failed to evaluated the 6 month competency of TP #4, due 12/17, and failed to evaluate the annual competency of TP #2 in 2017. Interview with current TC at approximately 10:30 a.m. confirmed the TC (laboratory director) had not performed competency assessments of testing personnel as required for 2016 and 2017.