Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1012581	06/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Virginia Oncology Associates	2790 Godwin Boulevard - Suite 101, Suffolk, VA	

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
D0000	An announced CLIA validation survey was conducted at Virginia Oncology Associates-Suffolk on June 7, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report form (CMS 209), hematology proficiency testing (PT) records, and interview, the laboratory failed to rotate proficiency testing among personnel performing patient hematology testing in 2016, 2017, and up the date of the survey on 6/7/18. Findings include: 1. Review of the laboratory's CMS 209 form revealed four (4) hematology testing personnel. 2. Review of the laboratory's American Proficiency Institute (API) PT attestation documentation (2016 Events 1-3, 2017 Events 1-3, and 2018 Event 1) revealed that testing personnel A performed six (6) of the seven (7) events reviewed. (See Personnel Code Sheet.) 3. In an interview with the laboratory manager and technical consultant on 6/7/18 at approximately 4:30 PM, it was confirmed that the laboratory failed to rotate hematology proficiency testing among all personnel responsible for performing patient testing on the Sysmex XN 1000 as outlined above.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish

	and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of the Laboratory Personnel Report Form (CMS 209), laboratory personnel files, and an interview, the laboratory did not document competency assessment for the technical consultant (TC) in calendar years 2016 and 2017. Findings include: 1. Review of the CMS 209, revealed that Testing Personnel E serves as Technical Consultant (TC). (See Personnel Code Sheet.) 2. Review of the personnel files revealed no competency assessments in 2016 and 2017 for Testing Personnel E in the role of TC. 3. In an interview with the laboratory manager and TC at approximately 4:30 PM on 6/7/18, it was confirmed that laboratory director did not have documentation of competency assessments for the TC in 2016 and 2017.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of the policies and procedures, quality control (QC) records, personnel competency assessments, and interview, the laboratory director (LD) did not delegate in writing, the job duties and responsibilities of technical consultant (TC) to the person performing the duties of TC from June 2016 to the date of the survey on June 7, 2018. Findings include: 1. Review of the policies and procedures revealed no documentation of the delegation of duties to the TC, in writing, by the LD. The inspector requested to review the delegation of duties. The documentation was not made available for review. 2. Review of QC records and reviews, and competency assessments of testing personnel performed in 2016 and 2017 revealed that TP E was performing the duties of TC in calendar year 2016 and up to the date of the survey. (See Personnel Code Sheet.) 3. In an interview with the lab manager and TC on 6/7/18 at approximately 4:30 PM, it was confirmed that the laboratory director (LD) did not delegate in writing, the job duties and responsibilities of technical consultant (TC) to TP E from June 2016 to the date of the survey on June 7, 2018.
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 a review of Laboratory Personnel Report form (CMS 209), laboratory personnel files, and interviews, the technical consultant failed to document annual competency assessments for hematology testing for two (2) of four (4) testing personnel in 2016 and 2017. Findings include: 1. Review of the CMS 209 form revealed four (4) testing personnel. 2. Review of the available laboratory personnel files revealed no hematology competency assessments in calendar years 2016 and 2017 for Testing personnel C and D. The inspector requested to review the competency documentation. The documentation was not available for review. (See Personnel Code Sheet.) 3. In interviews with the lab manager and technical consultant on 6/7/18 at approximately 4:30 PM and with the primary testing personnel on 6/11 /18 at approximately 12:00 PM, it was confirmed that the technical consultant failed to provide documentation of hematology competency assessments for the two (2) testing personnel outlined above in two (2) out of two (2) years reviewed.