

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0224067	(X3) Date Survey Completed 09/10/2019
Name of Provider or Supplier Virginia Cancer Specialists, Pc	Street Address, City, State 1100 N Glebe Rd, Suite 1600, Arlington, 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 recertification survey was conducted at Virginia Cancer Specialists, PC on September 10, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, quality control (QC) documentation, patient test logs, and interviews with the Technical Consultants (TC), the laboratory failed to follow the established policy for Complete Blood Cell (CBC) count QC performance of three (3) levels of QC each day of patient testing on one (1) day with thirty-six (36) patients tested during the twenty-one (21) months reviewed. Findings include: 1. Review of the laboratory's policies and procedures revealed a procedure, "Medonic M Series Hematology Analyzer", which stated, "Quality Control: 3 levels of Quality Control (QC) materials should be tested each day of patient testing prior to testing patient samples". 2. Review of Medonic M series QC documentation, from November 2017 to September 10, 2019, revealed the laboratory performed the low level of Boule Con diff QC material (lot #21905 exp 9/20/19) on June 11, 2019. No documentation of the normal or high control was found for June 11, 2019. The surveyor requested to review the documentation for the Boule Cone diff QC lot #21905 normal and high QC for June 11, 2019. The laboratory provided no documentation of the normal and high QC for June 11, 2019 for review. 3. Review of the Medonic Daily summary for June 11, 2019 revealed thirty-six (36) patients were</p>

tested and reported. 4. In an exit interview with TC 1 and TC 2 at approximately 11:35 AM, the findings were confirmed.