Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2108687	03/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Hematology Oncology Care Of Northern Virginia, Pc	1900 Opitz Boulevard Suites E & F, Woodbridge, 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 Hematology Oncology Care of Northern Virginia on March 14, 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:
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, procedures and policies, and interviews, the laboratory failed to test twelve (12) of twenty-five (25) proficiency testing samples in the same manner as patients in three (3) of five (5) events reviewed. Findings include: 1. Review of the laboratory's 2016 and 2017 American Proficiency Institute (API) PT records revealed the laboratory tested the following hematology PT samples multiple times: 2016 Event 3: samples # 11, # 13 and # 14 were assayed in duplicate, sample # 12 was assayed in triplicate, 2017 Event 2: samples # 6, # 7 and # 8 were assayed in duplicate, samples # 9 and # 10 were assayed in triplicate, 2017 Event 3: samples # 11, # 13 and # 14 were assayed in duplicate. The inspector inquired, at approximately 11:00 AM, if the laboratory routinely assays patient samples in duplicate and triplicate as noted with the proficiency samples. The primary testing personnel stated "No, we do not routinely run patients more than once. We have run the proficiency samples more often because we wanted to make sure we ran them correctly". 2. Review of the laboratory's procedure manual revealed a PT policy that stated "PT samples are tested exactly like patient samples, the same number of times and using the same personnel and methods as for patient testing." 3. An exit interview with the primary testing personnel on 3/14/18 at approximately 1:00 PM

	confirmed that the laboratory did not test twelve (12) of the twenty-five (25) reviewed PT samples in the same manner as patients for the 2016 and 2017 API events outlined above.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) documentation and an interview, the laboratory failed to retain attestation statements signed by the testing personnel for two (2) of five (5) PT events reviewed. Findings include: 1. Review of the laboratory's 2016 and 2017 American Proficiency Institute (API) hematology PT documentation, a total of five (5) events, revealed no testing personnel signed attestation statements for: 2016 Event 3, 2017 Event 1. The inspector requested to review the signed attestation documentation for the events listed above. No documentation was available for review. 2. An exit interview with the primary testing personnel on 3/14/18 at approximately 1:00 PM it was confirmed that the laboratory failed to retain copies of the API testing personnel attestation statements for the two (2) PT events outlined above in 2016 and 2017.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the Medonic performance verification records, patient accession test logs, and an interview, the laboratory failed to evaluate and verify accuracy and precision studies for the Medonic M-Series hematology analyzer prior to reporting one thousand nine hundred twenty (1,920) patient Complete Blood Count (CBC) results from October 28, 2016 to the date of the survey on March 14, 2018. Findings include: 1. Review of the laboratory's Medonic M-Series (Serial Number 30037) hematology analyzer performance verification documentation revealed that the laboratory relocated the analyzer from another physical address on October 28, 2016.

	The records did not include CBC accuracy and precision studies after the instrument was relocated and placed into use for patient CBC testing. The inspector requested to review documentation that the laboratory evaluated and verified the accuracy and precision performance criteria after the analyzer was relocated. No documentation was available for review. 2. Review of the accession test logs revealed that the laboratory had reported one thousand nine hundred twenty (1,920) patient CBC results from the date of the relocation on October 28, 2016 to the date of the survey on March 14, 2018. 3. An exit interview with the primary testing personnel at approximately 1:00 PM on 3/14/18 confirmed that the laboratory failed to document CBC accuracy and precision studies for the relocated Medonic-M (Serial Number 30037) analyzer prior to patient testing in October 2016.