Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0702896	(X3) Date Survey Completed 03/15/2018
Name of Provider or Supplier Hematology Oncology Assoc Of Fredericksburg	**Street Address, City, State** 4501 Empire Court, Fredericksburg, 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 Associates of Fredericksburg on March 15, 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:
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 chemistry proficiency testing (PT) documentation, and an interview, the laboratory failed to retain attestation statements signed by the laboratory director for two (2) of seven (7) events reviewed. Findings include: 1. Review of the laboratory's 2016 and 2017 American Proficiency Institute (API) chemistry PT documentation, a total of seven (7) events, revealed no laboratory director signed attestation statements for: 2016 Event 2 Chemistry Group 2 Module, 2017 Event 2 Chemistry Miscellaneous Module. The inspector requested to review the attestation documentation for the events listed above. No documentation was available for review. 2. In an exit interview with the lead laboratory technician on 3/15/18 at approximately 1:00 PM , it was confirmed that the laboratory failed to retain copies of

	the API laboratory director signed attestation statements for the two (2) PT events outlined above in 2016 and 2017.
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 a review of the laboratory's procedures, calibration verification records, analyzer's online test data, patient test logs, and interviews, the laboratory failed to perform twice annual calibration verification studies for sixteen (16) of sixteen (16) analytes according to the laboratory's written policy in calendar year 2017. Findings include: 1. Review of the procedure manual revealed a Quality Assurance (QA) policy to perform calibration verification for the Medica EasyRA chemistry testing once every six months. The policy states "Calibration Verification is required every 6 months on all analytes tested on the EasyRA analyzer". 2. Review of the laboratory's 2016 and 2017 EasyRA calibration verification records revealed that the verification studies were performed once (on 6/7/17) in calendar year 2017. The inspector noted that the laboratory calibration verification for the EasyRA was next performed nine (9) months later on 3/14/18. The inspector requested to review additional documentation of calibration verification performed in 2017. The documentation was not available for review. 3. Review of the EasyRA analyzer's online test data for analytes included for patient testing in 2017 and up to the date of the inspection, revealed the following sixteen (16) analytes: Albumin, Alkaline Phosphatase, Alanine Aminotranserase, Aspartate Aminotransferase, Blood Urea Nitrogen, Calcium, Choride, Carbon Dioxide, Creatinine, Glucose, Lactate Dehydronase (LDH), Magnesium, Potassium, Sodium, Total Bilirubin, Total Protein. 4. Review of the laboratory's Patient Test Count Log records revealed the following panels and tests were resulted during the three (3) month calibration verification lapse: Comprehensive Metabolic Panels: Three thousand two hundred sixty-nine (3,269), Magnesium: Three thousand eighteen (3,018), LDH: Four hundred twenty-four (424). 5. In an interview with the lead tech and at approximately 1:00 PM and a phone conversation with the technical consultant at approximately 1:30 PM on 3/15/17, it was confirmed that the

	laboratory failed to perform linearity validation studies according to the laboratory's written QA policy for the sixteen (16) Medica EasyRA chemistry test reagents outlined above in calendar year 2017.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of policies and procedures, Quality Assurance (QA) documentation, and interviews, the laboratory failed to establish and follow a policy for the comparison of hematology Complete Blood Count (CBC) test results performed on the two (2) Diatron Abacus 5 instruments for twenty-four (24) of the twenty-four (24) months reviewed. Findings include: 1. During a laboratory tour at approximately 10:00 AM, the inspectors noted patient CBC samples were being assayed on two (2) Diatron Abacus 5 hematology instruments. The instruments were labeled as: Instrument 1, Serial Number (SN) 510477, Instrument 2, SN 510475. 2. Review of the laboratory's policies and procedures revealed no QA plan to evaluate a comparison of CBC test results assayed on the two (2) Abacus 5 instruments. 3. Review of the laboratory's QA documentation from March 2016 through the date of the survey on 3/16/18 revealed no documentation or evaluation of CBC result comparison records for the two (2) hematology instruments listed above. 4. In an interview with the lead tech and at approximately 1:00 PM and a phone conversation with the technical consultant at approximately 1:30 PM on 3/15/17, it was confirmed that the laboratory failed to establish and document a comparison of hematology test results performed on the two (2) Diatron Abacus 5 instruments (SN 510477 and SN 510475) in twenty-four (24) of twenty-four (24) months reviewed.
D6022	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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of the laboratory's procedures, Medica EasyRA calibration verification records and analyzer's online test data, Quality Assurance (QA) documentation, and interviews, the laboratory director failed to ensure that QA policies were established and or followed during the twenty-four (24) of twenty-four (24) months reviewed. Refer to D5439 and D5775.