Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0915945	08/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Isabella Martire Md	8343 Cherry Lane, Laurel, MD	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and interview, the lab did not perform calibration of the hematology analyzer as required by the manufacturer. Findings: 1. The lab did not have a record of the calibration check performed in the beginning months of 2018 to meet the manufacturers six month calibration requirement, the previous calibration was performed July 10, 2017 and the next calibration was due in February of 2018; and 2. When interviewed in the afternoon on the day of the survey, lab staff stated that the calibration records for February 2018 were not available.
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 record review and interview, the lab did not establish the reportable range of the hematology analyzer and verify that the patient normal (reference) ranges are appropriate for the labs patient population. Findings: 1. The laboratory performed validation studies on the hematology analyzer in 2017; 2. The validation did not include data showing that the reportable range of the hematology analyzer and the patient normal ranges were established and verified; and 2. This was confirmed during interview with lab staff on the day of survey.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review, the lab did not perform corrective action procedures to ensure patient testing is not performed when quality control testing fails to meet the labs criteria for acceptability. Findings: 1. On 6/20/18 the results of the white blood cell (wbc) control tests (normal, low and high quality control checks) performed on the hematology analyzer failed to meet the labs criteria for acceptability and no corrective action was taken. The low wbc control result was 1.4 (acceptable range 1.9 to 2.7), the normal wbc control result was 5.1 (acceptable range 7.1 to 9.1) and the high wbc control result was 11.3 (acceptable range 15.1 to 20.1), all three controls results were on the low side of the expected range. On this day seven patient specimens were tested on the analyzer and there was no record that corrective actions were taken including reporting the problem on the labs monthly quality assurance log for June 2018 to report the problem to the lab director; 2. On July 6 (six patients tested), 9 (four patients tested) , 11 (eleven patients tested) , 13 (ten patients tested) and 16 (three patients tested) of 2018, the hematology lab did not report quality control results from the analyzer. There was no corrective action documented in the monthly quality assurance reports to the director for July of 2018, and there were no corrective action records on each day of testing; 3. On June 22 (nine patients tested), 25 (six patients tested) and 29 (13 patients tested) of 2018 the hematology lab did not report quality control results. On the back of the three blank checks performed daily during startup of the hematology analyzer, it was reported that quality control testing was not performed. There was no corrective action documented in the monthly quality assurance reports to the lab director for June of 2018, and there was no documentation showing that the lab took corrective action on each day of testing.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel

	who performed the test(s). This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the lab did not ensure that hematology quality control test records were initialed by the testing person and reviewed by the lab director. Findings: 1. Printed on the the labs quality control records are signature lines for the testing person to document their identity, and a second for the director to sign and show her review of the results for each daily control reagent (low, normal and high control reagents); 2. In March 2018, 35 of 72 quality control test results, were not initialed by the testing person and also did not include the lab directors reviews. In April 2018, all 58 quality control test results, were not initialed by the testing person and also did not include the lab directors reviews and in August of 2018 all 34 quality control control test results were not initialed by the testing person and did not include the lab directors reviews; and 3. This was confirmed during interview with lab staff on the morning of the survey.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) 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. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: 1. Based on record review and interview, the laboratory (lab) director did not document training for testing person A, the lab did not have training record for testing person A even though she was performing hematology lab tests using the hematology analyzer, the lab did not have safety training records showing that testing person A was also provided training in chemical hygiene and biological hazards. This was confirmed during interview with staff on the day of survey. 2. Based on record review and interview, the laboratory (lab) director did not have an education equivalency evaluation performed for testing person A to evaluate her foreign academic credentials so that she can be credentialed by CLIA for moderate complexity testing. This was confirmed during interview with lab staff on the day of survey.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview, the lab did not ensure the director reviewed

	and maintained the written procedures manual. Findings: 1. The lab director did not document her annual review of the labs standard operating procedure manual (SOPM) for 2018 as indicated in the review page for the SOPM. In addition this review cover page was not updated to show procedural changes when the lab replaced its hematology analyzer with a different model and began patient testing using this new hematology analyzer in 2017, the last documented revision on the review page was dated 6/1/10; 2. The addendum in the SOPM, the hematology reference ranges, pages 17 and 19 for the hematology analyzer all refer to the name of the analyzer that the lab replaced in 2017; 3. The lab also needs to update its safety data sheets for reagents used in the new analyzer and cleaning chemicals, the safety data sheets were reviewed with lab staff and it was confirmed that they needed updating.