Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0970932	08/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lori Mcauliffe Md Pa	405 S Pasadena Ave South, Saint Petersburg, FL	

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 Lori McAulifffe MD PA on 08/28/19. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 record review of the CMS 209 Laboratory Personnel Report, laboratory procedure manual, and One World Accuracy Accutest Hematology proficiency testing records for White Blood Cell Count, Red Blood Cell Count, Hemoglobin, Hematocrit, Mean Corpuscular Volume, Mean Corpuscular Hemoglobin, Mean Corpuscular Hemoglobin Concentration, Platelets, Granulocytes, Lymphocytes, and Monocytes, and interview with Testing Personnel #A, the laboratory failed to have all testing personnel (#A, #B, #C, and #D) rotate through the testing of proficiency testing for two out of two (2017-2019) years reviewed. Findings included: Record review of the CMS 209 Laboratory Personnel Report signed by the Laboratory Director on 07/17/19 showed the laboratory had 4 testing personnel (#A, #B, #C, and #D). Record review of the laboratory's manual revealed "Proficiency Testing" procedure that stated "all staff performing the testing should sign in the attestation spaces provided on the data sheet." Record review of the proficiency testing revealed that Testing Personnel #A had signed the attestation statement for 2 proficiency testing Events (1st Event 2018, and 1st Event 2019) out of 6 (3rd Event 2017, 1st, 2nd, and 3rd Event 2018, and 1st and 2nd Event 2019) proficiency test Events. Record review of the proficiency testing also revealed that the 2nd Event of 2019 indicated Testing Personnel #A had performed the proficiency testing but Testing Personnel #A had not signed the

	attestation statement. Record review of the proficiency testing also revealed that the 3rd Event of 2017 attestation statement had not been signed by the testing personnel. Testing Personnel #A signed the 3rd Event of 2017 attestation statement during the 08 /28/19 survey after being shown the signature was missing. On 08/28/2019 at 10:30 AM, Testing Personnel #A stated she had performed all proficiency testing for two out two years (3rd Event 2017, 1st, 2nd, and 3rd Event 2018, and 1st and 2nd Event 2019). She did not know proficiency testing must be rotated through all testing personnel to include Testing Personnel #B, #C, and #D.
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 record review of One World Accuracy Accutest Hematology proficiency testing records, the laboratory procedure manual, and interview with Testing Personnel #A, the laboratory did not maintain all of the proficiency testing records and did not have the required signatures on all of the documentation for two of two years reviewed (2017-2019). Findings include: Record review of the laboratory procedure manual revealed the "Proficiency Testing" procedure stated "The Laboratory Director or Technical Consultant should sign and date the data sheet and all staff performing the testing should sign in the attestation spaces provided on the data sheet." (Attestation statement and signature blanks for laboratory director and testing personnel were present at the bottom of the data sheet.) In addition, the procedure stated "Retain a copy of all data sheets, attestation sheets, worksheets, and instrument printouts for 2 years." Record review of the proficiency testing revealed attestation statements for 3 proficiency testing events (3rd Event 2017, 3rd Event 2018, and 2nd Event 2019) out of 6 (3rd Event 2017, 1st, 2nd, and 3rd Event 2018, and 1st and 2nd Event 2019) had not been signed by the Laboratory Director and Testing Personnel. Testing Personnel #A did sign the 2017 3rd Event during the survey on 08/28/19. Record review of the proficiency testing revealed 1 attestation statement (2nd proficiency testing event 2018) was missing out of 6 proficiency testing events (3rd Event 2017, 1st, 2nd, 3rd 2018 Event, and 1st and 2nd Event 2019). Interview on 08/28/2019 at 12:15 PM with Testing Personnel #A confirmed the attestation statements had not been signed for 3rd Event 2017, 3rd Event 2018, and 2nd Event 2019 and the attestation statement for 2nd Event 2018 was missing.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and

	test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview with Testing Personnel #A, the laboratory failed to document the humidity for 2 out of 2 years (2017-2019) . Findings Included: Record review of Plan of Correction for unsuccessful Red Blood Count proficiency testing (07/19) revealed the laboratory had replaced their Abbott Cell - Dyn 1800 with an Abbott Cell - Dyn Emerald 02/19 and this instrument was replaced with another Emerald analyzer on 07/15/19. Review of the Abbott Cell - Dyn 1800 manufacturer's instructions revealed that the operational humidity was 85% maximum and the Abbott Cell - Dyn Emerald Installation Instructions stated that operational humidity maximum was 80%. Review of records for 2 out of 2 years (2017-2019) revealed no documentation of humidity was documented for the room where the hematology testing was performed. An interview on 08/28/19 at 12:25 PM with Testing Personnel #A revealed she did not know humidity needed to be documented each day of hematology testing.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on record review and interview with Testing Personnel #A, the Technical Consultant failed to ensure that all competency records were retained for 4 out 4 testing personnel (#A, #B, #C, and #D) for 2 out of 2 years reviewed (2017-2019). Findings included: Review of the personnel records revealed that competency records were missing for 4 out of 4 testing personnel (#A, #B, #C, and #D) for two out of two years. Interview on 08/28/2019 at 9:45 AM with Testing Personnel #A revealed she was performing an annual review but did not keep the records. She was unaware of the need to maintain the records for 2 years.