Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2136938	08/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
College Park Medical Center	4701 Melbourne Place, College Park, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on quality control (QC) record review and interview with the laboratory staff, the laboratory did not retain QC records for at least 2 years. Findings: 1. Review of hematology QC records from May to July, 2018 showed that on 5/14/18 the platelet was out of range/unacceptable for the low level control. The QC was repeated but the print out for the initial run (out of range control) was not available at the time of the survey; and 2. On 5/18/18, the platelet was out of range/unacceptable for the low level control. The QC was repeated 3 times before the control was acceptable but the print outs for the out of range controls were not not available at the time of the survey. 3. During an interview on 7/19/18 at 2:00 PM, the laboratory staff confirmed that the laboratory did not retain QC records for at least 2 years.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the standard operating procedure manual (SOPM) and interview

	with the technical consultant (TC), the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory system. Findings: 1. A review of the SOPM showed that there was no written policy for conducting quality assurance (QA) reviews of the laboratory. 2. During an interview on 7/19/18 at 12:00 PM, the TC confirmed that there was no written QA policy in the SOPM.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) review and interview with the laboratory staff, the laboratory did not provide the testing personnel with written preanalytical, analytical, and post analytical policies and procedures for testing with the Coulter Ac.T diff 2 hematology analyzer. Findings: 1. A review of the SOPM showed that there were no written procedures for patient preparation; specimen collection, labeling, storage, preservation, processing, and referral; criteria for specimen acceptability and rejection; control procedures; corrective action to take when control results fail to meet the laboratory's criteria for acceptability; the laboratory's system for entering results in the patient record and reporting patient results; and a description of the course of action to take if the test system becomes inoperable. 4. During an interview on 7/19/18 at 2:00 PM, the laboratory staff confirmed that the SOPM did not contain written preanalytical, analytical, and post analytical policies and procedures for testing with the Coulter Ac.T diff 2 hematology analyzer.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) review and interview with the laboratory staff, the laboratory did not ensure that the SOPM was signed and dated by the laboratory director (LD). Findings: 1. A review was performed of the SOPMs available in the laboratory, including the "Hazard Communication and Safety Program," "Coulter Ac.T diff 2 Hematology Analyzer," and "Beckman Coulter Guide and Reference" manuals. During an interview, laboratory staff stated that they use the "Beckman Coulter Guide and Reference" manual as a reference for daily maintenance, QC, and running of the hematology analyzer; and 2. This review showed that 3 of 3 procedure manuals were not approved (signed and dated) by the LD. 3. During an interview on 7/19/18 at 2:00 PM, the laboratory staff confirmed that the current SOPM was not signed and dated by the LD.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory staff, the laboratory failed to ensure that hematology controls and reagents were labeled with the expiration date. Findings: 1. During a tour of the laboratory at 10:15 AM, it was observed that the opened and in use hematology controls in the laboratory refrigerator and the in-use "CBC diff Ac.T Pak Reagent Kit" on the hematology analyzer were not labeled with the expiration date. 2. During an interview on 7/19/18 at 2:00 PM, the laboratory staff confirmed that the hematology controls and reagents in use were not labeled with the expiration date.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory staff, the laboratory did not ensure that quality control (QC) materials and reagents for the hematology analyzer were not used after the expiration date. Findings: 1. A review of hematology records showed that the laboratory did not have a complete record of the lot numbers and expiration dates of the QC and reagents used for the Coulter Ac.T diff 2 hematology analyzer. 2. During an interview on 7/19/18 at 2:00 PM, the laboratory staff confirmed that there were no lot numbers or expiration dates documented for the QC and reagents used for hematology testing.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g)

	(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) record review and interview with the laboratory staff, the laboratory did not ensure that QC results met the laboratory's criteria for acceptability prior to reporting patient results. Findings: 1. The laboratory utilizes a Coulter Ac.T diff 2 to perform hematology testing on patient specimens. The laboratory tests 3 QC reagents daily on the hematology analyzer. QC records from April to July, 2018 were reviewed. 2. On 5/7/18 and 5/14/18 the background count failed for platelets after the daily startup. The background count was not repeated prior to testing QC and patient specimens; and 3. On 6/7/18 the high level of QC (lot number 89800, expiration date 8/27/18) was run in the file for the normal control (lot number 79800, expiration date 8/27/18). The results were flagged as unacceptable. The high control was not run in the correct file for the high control; and 4. On 6/9/18 the high level of QC was run in the file for the normal control. The results were flagged as unacceptable. The high control was also run in the correct file for the high control; and 5. On 6/18/18 the high level of QC was run in the file for the normal control. The results were flagged as unacceptable. The high control was also run in the correct file for the high control. 6. During an interview on 7/19/18 at 2:00 PM, the laboratory staff confirmed that the laboratory did not ensure that QC results were acceptable prior to reporting patient hematology results.
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 standard operating procedure manual (SOPM) review and interview with the laboratory staff, the laboratory director (LD) did not ensure that an approved and signed SOPM was available to all laboratory testing personnel. Findings: 1. A review of the SOPM showed that the SOPM had not been reviewed or signed by the laboratory director. Refer to D5407; and 2. The LD did not ensure that the SOPM included written preanalytical, analytical, and post analytical policies and procedures for testing with the Coulter Ac.T diff 2 hematology analyzer. Refer to D5403. 3. During an interview on 7/19/18 at 2:00 PM, the laboratory staff confirmed that the LD did not ensure that an approved and signed SOPM was available to all laboratory testing personnel.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory staff, the laboratory director (LD) did not specify in writing the duties and responsibilities of each person involved in the performance of preanalytic, analytic, and postanalytic phases of testing. Findings: 1. A review of the standard operating procedure manual (SOPM) showed that there was no description of duties and responsibilities for the LD, clinical consultant, technical consultant, and testing personnel. 2. During an interview on 7/19 /18 at 2:00 PM, the laboratory staff confirmed that there was no list of duties and responsibilities for the LD, clinical consultant, technical consultant, and testing personnel in the SOPM.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant (TC), the TC was not documenting a regular review of the laboratory worksheets, quality control (QC) records, and hematology analyzer maintenance records. Findings: 1. The laboratory started testing in April, 2018. Laboratory records were reviewed from April to July, 2018. The records did not include documentation of quality assurance (QA) reviews performed by the TC. 2. During an interview on 7/19/18 at 12:00 PM, the TC stated that he "comes to the lab weekly to review QC" and that he also communicates with laboratory staff when he is not in the laboratory. The TC confirmed that there was no written documentation of weekly visits or a log of communication with laboratory staff.