Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0675384	01/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Capital Health Hematology/Oncology	40 Fuld Street Suite 404, Trenton, NJ	

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
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to attain at least 80% or more for Hematology tests performed on the Medonic M series analyzer with the American Academy of Family Physician (AAFP) in the 2018-B events. The findings include: 1. The laboratory scored 60% in 2018 - B on samples HD-6 and HD-7 for the following parameters; a. White Blood Cell Counts b. Lymphocyte % c. Monocyte mixed % d. Granulocyte % e. Red Blood Cells f. Hemoglobin g. Hematocrit h. Mean Corpuscular Volume (MCV) i. Platelet 2. There was no documented evidence the failures mentioned above were investigated. 3. The TP #5 listed on CMS form 209 confirmed on 1/31/19 at 10:40 am that the laboratory failed to attain an 80% or more for Hematology tests.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to evaluate results when they received an unacceptable score in Hematology tests performed on the Medonic M series analyzer with the American Academy of Family Physician (AAFP) in the 2017-

	C event. The findings include: 1. The laboratory received "Fail" in 2017 - C on samples HD-13 for Mean Corpuscular Volume (MCV) and HD-15 for Lymphocyte % . 2. There was no documented evidence that the laboratory investigated the failures. 3. The TP #5 listed on CMS form 209 confirmed on 1/31/19 at 10:42 am that the laboratory did not perform and document an evaluation of unacceptable PT results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual, review of Quality Control (QC) data and interview with the Testing Personnel (TP), the laboratory failed to follow the QC lot to lot verification procedure from September 2017 to March 2018. The findings include: 1. The PM stated " Before putting a new lot of control materials in use verify the new control by parallel testing with the current lot." 2. The laboratory did not parallel test new QC lots as follows: a. Lot 21705 expired 9/28/17 - New Lot 21708 was verified 10/3/17 b. Lot 21708 expired 12/27/17 - New Lot 21711 was verified 1/2/18 c. Lot 21711 expired 3/27/18 - New Lot 21802 was verified 3/28/18 3. The TP # 5 listed on the CMS form 209 confirmed on 1/31/19 at 11:50 am that the QC procedure above was not followed.
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 surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure for imminently life-threatening test results, or panic or alert values on the Medonic M series analyzer

	from March 2017 to the date of survey. The TP #5 listed on CMS form 209 confirmed on 1/31/19 at 12:10 pm that the laboratory did not establish the above procedure.
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 lack of Performance Specification (PS) records and interview with the Testing Personnel (TP), the laboratory failed to ensure that PS procedures were performed on the Medonic Series M analyzer from March 2017 to the date of survey. The finding includes: 1. There was no documented evidence Accuracy, Precision, Linearity, and Reference Range validation were performed. 2. The TP #5 listed on the CMS form 209 confirmed on 1/31/19 at 11:15 am that PS were not performed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor review of the Maintenance Record (MR) and interview with the Testing Personnel (TP), the laboratory failed to perform and document maintenance as specified by the manufacturer on the Medonic Series M analyzer used in Hematology Testing in the calendar year 2018. The findings include: 1. MR records revealed monthly clot prevention maintenance was not performed from January to August and in December 2018. 2. A review of the MR revealed there was no documented evidence six month maintenance was performed in 2018. 3. The TP #5 listed on CMS form 209 confirmed on 1/31/19 at 1:30 pm that maintenance as specified by the manufacturer was not performed.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as

	acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of Calibration Verification (CV) records, Manufacturer Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory failed to use calibration material appropriate for the Medonic M series analyzer used for Hematology tests from March 2017 to the date of the survey. The findings include: 1. A review of the Streck MPI for CV assessment material used in March and October 2017 revealed that the Medonic M series analyzer was not listed for acceptable calibration values. 2. The TP #5 listed on CMS form 209 confirmed on 1/31/19 at 12: 30 pm the laboratory used the Streck CV material for the calibration upon installation of the instrument and the calibration in October 2017. 3. The TP #5 listed on CMS form 209 confirmed on 1/31/19 at 12:30 pm the laboratory failed to use calibration material appropriate for the Medonic M-series analyzer.
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 surveyor review of Calibration Verification (CV) records and interview with the Testing Personnel (TP), the laboratory failed to perform and document CV procedures at least once every six months for Hematology Testing on the Medonic M series analyzer in the calendar year 2018. The finding includes: 1. The laboratory last performed CV in October 2017. 2. The TP #5 listed on CMS form 209 confirmed on 1 /31/19 at 12:00 pm CV was not performed every six months.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.

	1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor's review of the laboratory's records and interview with the Laboratory Director (LD), the LD failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from March 2017 to the date of the survey. 1. The LD failed to ensure Proficiency Testing results were reviewed. Cross refer to D6018. 2. The LD failed to ensure a Quality Assessment procedure was established and maintained. Cross refer to D6021. 3. The LD failed to have appropriate education and training documented on all testing personnel. Cross refer to D6029. 4. The LD failed to ensure a Competency Assessment procedure was established and maintained. Cross refer to D6030. 5. The LD failed to have an approved Procedure Manual. Cross refer to D6031. 6. The LD failed to provide Job Descriptions for Testing Personnel. Cross refer to D6032.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that all PT results received were reviewed by the appropriate staff to identify any problems that require corrective action for Hematology testing performed with American Academy of Family Physician (AAFP) in the 2017-C and the calendar year 2018. The TP #5 listed on CMS form 209 confirmed on 1/31/19 at 11:00 am that the PT results were not reviewed.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of a Quality Assessment (QA) policy and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that a QA program was

	established and the Plan of Correction (POC) was followed from 8/22/16 to the date of survey. The findings include: 1. Plan of Correction (POC) stated "QA is performed yearly and evaluated and signed by the LD" but there was no documented evidence POC was followed. 2. The TP #5 listed on CMS form 209 confirmed on 1/3/19 at 11: 50 am that the laboratory did not have a QA program. Note: This deficiency was cited on a previous survey preformed on 8/22/16.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: a. Based on surveyor review of the Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to have appropriate education records for all Testing Personnel (TP) on file from 8/22/16 to the date of the survey. The finding includes: 1. Plan of Correction (POC) stated "All TP folders updated with highest level of diploma" but there was no evidence POC was followed for TP #5. 2. TP #5 listed on CMS form 209 did not have education records. 3. The TP confirmed on 1/31/19 at 10:00 am education records were not in the PF. Note: This deficiency was cited on survey preformed on 8/22/16. b. Based on surveyor review of the PF and interview with the TP, the LD failed to have training documentation for hematology tests on the Medonic Series M analyzer on file for TP #3 from March 2017 to the date of the survey. The TP #5 listed on CMS form 209 confirmed on 1/31/19 at 10:00 am training records were not in the PF for TP #3.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to establish a Competency Assessment (CA) procedure with the required elements for Hematology tests

	performed on the Medonic M series analyzer from March 2017 to the date of the survey. The TP #5 listed on CMS form 209 confirmed on 1/31/19 at 10:40 am that a CA procedure was not established.
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 surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the Laboratory Director failed to have an approved procedure manual available for Hematology testing at the time of the survey. The TP #5 listed on CMS form 209 confirmed 1/31/19 at 11:15 am an approved PM was not available.
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 surveyor review of the Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to specify in detail the duties and responsibilities for two out of two TP (currently performing testing) engaged in the performance of preanalytical, analytic and post analytic phases for Hematology tests from 8/22/16 to the date of survey. The TP # 5 listed on CMS form 209 confirmed on 1/31/19 at 10:15 am that the LD did not specify the duties and responsibilities of TP.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by:

	Based on surveyor review of the Personnel Files, Competency Assessment (CA) records and interview with the Testing Personnel (TP), the Technical Consultant (TC) failed to perform CA from 8/22/16 to the date of survey. The findings include: 1. TP #5 stated she had a High School Diploma on the date of the survey. 2. TP #5 education record was not on file on the date of the survey. 3. The TP #5 performed CA on four of five TP. 4. The CA was not performed by qualified personnel. 5. The TP #5 listed on CMS form 209 confirmed on 1/31/19 at 10:15 am that the CA was not performed by TC.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on surveyor observation the analyzer, analyzer printout and interview with the Testing Personnel (TP), the TP failed to ensure that test analyses performed on the Medonic M series had correct time programmed on the date of the survey. The findings include: 1. The TP was observed performing test at 11:36 am but the analyzer printout had 12:08 pm. 2. The TP was not aware that the analyzer clock was not accurate and could not confirm the extent of the issue. 3. The TP # 5 listed on CMS form 209 confirmed on 1/31/19 at 12:30 pm that laboratory failed to follow laboratory procedures for test analyses.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personal (TP), the TP failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Medonic M series analyzer from March 2017 to the date of the survey. The TP #5 listed on CMS form 209 confirmed on 1/31/19 at 11:45 pm that trends and shifts were not reviewed.