Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0892180	10/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Gonzaga Pediatrics & Family Medicine	957 National Highway, Cumberland, 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
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 review of the hematology proficiency testing (PT) records, procedure manual and interview with the testing person, the laboratory failed to ensure that all PT records were being saved; PT summaries were being reviewed by the laboratory director or designee; the testing person who performed the test initialed the instrument printouts in the same manner as the patients; the final results were being reviewed by the laboratory director or designee; and the records were maintained for two years as required. Findings: 1. The PT records from the third event of 2016 through the second event of 2018 (6 events) were reviewed. 2. The PT records showed that 4 of the 6 events did not include a copy of the completed PT worksheet showing the results submitted to the PT agency. 3. The PT records showed that the attestation worksheets for 6 of the 6 events were not signed by the laboratory director or the designee. The attestation worksheets were signed by a testing person and the laboratory director's son. The Personnel Laboratory Report (CLIA) (CMS-209) listed the laboratory director as the technical consultant. The laboratory director's son is not listed on the CMS-209 and the testing person is not qualified to be the designee. 4. The PT records

	showed that the instrument printouts from 4 of the 6 events did not include the initials of the person who performed the tests and signed the PT attestation sheet. The procedure manual requires the testing person to initial the instrument printout with the patient's results. 5. The PT records showed that the final results for 5 of the 6 events were not signed by the laboratory director or the designee and 3 of the 6 had no signature showing that the document had been reviewed. 6. The policy and procedure manual did not identify who was the qualified designee for signing the attestation worksheets and the final review of the PT results. The persons who signed the attestation worksheets and final reports were not listed on the CMS-209 or were not qualified with a Bachelor of Science (4 year degree) and 2 years' experience in the specialty of hematology. 7. During the survey on 10/12/2018 at 2:00 PM the testing person confirmed that the PT records were not maintained for two years and signed by the appropriate laboratory staff.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's record system and interview with the testing personnel, the laboratory failed to maintain a record system that included retention of quality assessment records for at least 2 years. Findings: 1. Review of the "Medonic Weekly QC Sign Off" worksheets showed that there were no records available prior to the second week of July 2017. 2. Review of the "Monthly Laboratory Staff Responsibilities Checklist" worksheet showed that there were no records available prior to September 2017. 3. Review of the "Maintenance Medonic M-Series Hematology Analyzer" worksheets showed that there were no maintenance records available prior to June 2018. 4. Review of the proficiency testing records showed that 4 of the 6 events did not include a copy of the completed PT worksheet showing the results submitted to the PT agency. Cross refer to D2015 for details. 5. Review of the "Corrective Action Log for Daily Control Procedures" worksheets showed that there were no records available prior to February 15, 2018. 6. Review of the "Laboratory Director Monthly Review" worksheets showed that there were no records prior to January 2018. 7. Review of the hematology monthly cleaning records from January through October 2018 showed that the months of February through July 2018 were missing. In addition all the hematology monthly cleaning records from 2017 were missing. 8. Review of the "Daily Log" for recording the room and refrigerator temperature and humidity showed that there were no records prior to January 2018. 9. During the survey on 10/12/2018 at 2:00 PM and confirmed on 10/26/2018 at 11:45 AM the testing person confirmed that the laboratory records could not be found and were not being maintained for two years as required.
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: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 11/21/2016 for not ensuring that the procedure manual included written instructions for all procedures performed by the testing personnel to ensure that they perform accurate and reliable testing on patient specimens. The plan of correction stated that these policies and procedures would be provided to the testing personnel. Based on review of the procedure manual and interview with the testing personnel, the laboratory's procedure manual failed to include all policies and procedures required for the testing personnel to perform their jobs accurately and reliably. 1. The laboratory staff complete a worksheet labeled "Monthly Laboratory Staff Responsibilities Checklist." The checklist and instructions on how to complete the checklist were not found in the laboratory's policies and procedure manual. 2. According to the lead testing person the "control summary report" for the hematology analyzer is printed monthly. The lead testing person highlights all the quality control results that are out of the acceptable limits and provides these to the LD for review. The procedure manual does not include written instructions for this task. 3. According to the lead testing person when quality controls are tested each day they are tested in the capillary mode and the venous mode. There are no written procedures explaining how this system works and how to evaluate the capillary mode separately from the venous mode. 4. Review of the room temperature and refrigerator temperature worksheets showed that the acceptable temperature ranges were not listed on the worksheet. The procedure manual also did not list the acceptable temperature ranges. 5. Review of the "Lab Result Process" procedure did not include instructions for how to scan and attach patient results to the electronic medical record (EMR). The procedure did not include instructions for what to do when the analyzer or EMR becomes inoperable. 6. Review of the procedure manual shows that there are no written policies and procedures instructing the testing personnel on what information is printed from the hematology analyzer each month for review by the technical consultant. 7. Review of the procedure manual showed that the laboratory did not have written policies and procedures for the evaluation and documentation of quality control (QC) results. There were no written instructions defining the sequence of events to follow when evaluating unacceptable QC results, e.g., when to repeat QC; when to calibrate; when to test fresh QC materials; when to call the technical consultant; and how to document the corrective actions taken. 8. During the survey on 10/12/18 at 2:00 PM the testing personnel confirmed that the procedure manual did not include policies and procedures for all the activities performed by the laboratory staff.
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 review of the procedure manual and interview with the testing person, the laboratory failed to have all the policies and procedures approved by the current laboratory director listed on the CLIA certificate. Findings: 1. Review of the procedure manual showed that the procedure labeled "Responsibilities and Duties of Employees" was signed and dated on 10/02/2018 by someone other than the laboratory director listed on the CLIA certificate. 2. During the survey on 10/12/18 at 2:00 PM the testing personnel confirmed that the procedure in question was signed by the current laboratory director's son.
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 review of the hematology quality control (QC) records and interview with the testing personnel, the laboratory failed to ensure that reagents and QC materials used in the laboratory were not used after their expiration date. Findings: 1. Review of the laboratory's QC records and the "Control Summary Report" printouts showed that the records did not include documentation showing when the laboratory switched from one lot number of QC materials and reagents to the new lot of QC materials and reagents. The records failed to show that QC materials and reagents were not used past their expiration dates. 2. During the survey on 10/12/2018 at 2:00 PM the testing person confirmed that the laboratory records that were available did not show when the laboratory switched to a new lot number and expiration date of the QC materials and reagents used to perform testing in the laboratory.
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: I. Based on review of the maintenance worksheets for the Medonic M-Series (hematology analyzer) and interview with the testing personnel, the laboratory failed to ensure that the maintenance for the hematology analyzer was performed at the frequency required by the manufacture to provide quality laboratory services. Findings: 1. The maintenance worksheets for the hematology analyzer for June through September 2018 were reviewed. The section labeled "Monthly Maintenance (User Manual Section 8.2)" showed that the following maintenance was not being

	performed and documented. The sections labeled "Monthly Cleaning (Hypochlorite)" and "Clot Prevention (Enzymatic)" require the laboratory to document the Lot number, Bottle number, Date and Tech each month the maintenance is performed. The maintenance worksheets for June through September 2018 showed that these activities had not been performed and documented. 2. The maintenance worksheets for the hematology analyzer for June through September 2018 were reviewed. The section labeled "Six Month Maintenance (User Manual Section 8)" requires the laboratory to document the Lot number, Date and Tech every six months when the maintenance is performed. The maintenance worksheets for June through September 2018 showed that these activities had not been performed and documented. 3. The maintenance worksheets for the hematology analyzer for June through September 2018 were reviewed. The section labeled "Calibration (User Manual Section 7)" requires the laboratory to document the Lot number, Date and Tech when the maintenance is performed. The maintenance worksheets for June through September 2018 showed that these activities had not been performed and documented. 4. According to the testing personnel the laboratory has been using the same hematology analyzer for over two years. At the time of the survey the laboratory staff could not produce maintenance records prior to June 2018. 5. During the survey on 10/12/18 at 2:00 PM the testing personnel confirmed that the maintenance worksheets failed to include documentation of the required information to ensure that the laboratory was maintaining the hematology analyzer per the manufacturer's instructions and that the laboratory was not keeping maintenance records prior to June 2018. II. Based on review of the corrective action logs for the hematology analyzer and interview with the testing personnel, the laboratory failed to ensure that the corrective actions were documented on the logs when required. Findings: 1. The "Corrective Action Log for Daily Control Procedures" showed that the last documented corrective action was documented on 05/10/18. According to the testing personnel the hematology analyzer was not working from 03/30/2018 through 04/17/18. The laboratory could not perform the tests on the proficiency testing samples because the quality control results failed and the analyzer was waiting to have maintenance performed. This event was not documented on the "Corrective Action Log for Daily Control Procedures." 2. During the survey on 10/12/18 at 2:00 PM the testing personnel confirmed that the quality control failures were not documented on the required corrective action log.
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 record review and interview, the laboratory director failed to provide oversight of the overall operation of the laboratory (D6004); failed to ensure that the PT records reviewed by the appropriate designee and were maintained for the required two years and failed to identify problems with the PT results and ensure corrective actions were taken and documented (D6018); failed to provide a written corrective action plan for the testing personnel to follow when investigating proficiency testing failures (D6019); failed to ensure that the established quality control (QC) and quality assurance (QA) procedures to monitor the overall operation of the laboratory were maintained by the current laboratory director (D6022); failed to ensure that the quality control program was maintained to provide quality laboratory services (D6023); failed

	to ensure that all testing personnel received initial training by the qualified technical consultant (D6029); and failed to specify in writing, the responsibilities and duties of each person engaged in the performance of the laboratory testing (D6032).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to provide oversight of the overall operation of the laboratory by ensuring that the procedure manual was current and testing personnel are in compliance with the regulations. Findings: 1. The "Laboratory Personnel Report (CLIA)" (CMS-209) form identifies the Laboratory Director, Clinical Consultant, and Technical Consultant as the same person. 2. The laboratory records, i.e., quality control worksheets, monthly laboratory staff responsibilities checklists, quality assurance reviews, maintenance records, and temperature charts were not being reviewed by the technical consultant to evaluate the competency of the testing personnel to ensure accurate and reliable test results. 3. The testing person stated that the laboratory director's son and not the laboratory director listed on the CMS-209 was reviewing the laboratory records. 4. During the survey on 10/12/2018 at 2:00 PM the testing personnel confirmed that the laboratory director's son and not the laboratory director listed on the CMS-209 was reviewing the laboratory records.
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: I. Based on review of the hematology proficiency testing (PT) reports and interview with the testing personnel, the laboratory director failed to ensure that the PT records were reviewed by the appropriate designee and were maintained for the required two years. Cross refer to Tag D2015. II. Based on review of the hematology PT records and interviewe with the testing personnel, the laboratory director failed to identify problems with the PT results and ensure corrective actions were taken and

	documented. Findings: 1. The PT records showed that the laboratory was not able to participate in the first event of 2018. On 3/30/18 the PT agency advised the laboratory to submit the PT paperwork with the comment "Instrument out of service" and then test the specimens when the analyzer was working. 2. On 4/17/18 the hematology analyzer was working and testing patient and PT samples. The laboratory found the peer group results in the PT summaries but failed to perform a self-evaluation and compare the laboratory values with the summary values to determine if the results were acceptable. 3. During the survey on 10/12/18 at 2:00 PM the testing personnel confirmed that the laboratory's investigation failed to include a comparison of the peer group results with the laboratory's results tested on 4/17/18 to ensure that the laboratory received a passing grade for the first event of 2018.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with laboratory staff, the laboratory director failed to provide a written corrective action plan for the testing personnel to follow when investigating proficiency testing failures. Cross refer to Tag D2015.
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 review of the procedure manual and interview with the testing personnel, the laboratory director failed to ensure that there were approved quality control (QC) and quality assessment (QA) policies and procedures to monitor the overall operation of the laboratory to assure the quality of the laboratory services. Findings: 1. At the time of the survey the laboratory's procedure manual did not include written QC policies and procedures for the testing personnel to follow. Cross refer to Tag D5403 #7 for details. 2. At the time of the survey the laboratory's procedure manual did not include written QA policies and procedures for the testing personnel to follow. 3. During the survey on 10/12/18 at 2:00 PM the testing personnel confirmed that the procedure manual did not include a written QA program designed to monitor the activities of the laboratory. Please note: The QA program must include, but is not limited to the following: patient test management, testing methods, quality control, proficiency

	testing, comparison of test results, relationship of patient information to patient test results, personnel assessment, communication, complaint investigation, and quality assessment reviews.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of the maintenance worksheets for the Medonic M-Series (hematology analyzer) and interview with the testing personnel, the laboratory director failed to ensure that the maintenance was being performed and documented to provide quality laboratory services. Cross refer to Tag D5429 for details.
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: Based on review of the "Medonic M Series Training Check List" evaluation forms and interview with the testing personnel, the laboratory director acting as the technical consultant failed to ensure that all testing personnel received initial training by the qualified technical consultant. Findings: 1. The laboratory currently has six testing persons listed on the "Laboratory Personnel Report (CLIA) (CMS-209)." The laboratory director is acting as the technical consultant. 2. The testing personnel evaluation records for 2017 and 2018 were reviewed. Three of the six testing persons had no initial evaluations performed and documented prior to performing laboratory tests. 3. There was no training documented on the required check list for testing person #2, #5, and #6 listed on the CMS-209. 4. During the survey on 10/12/2018 at 2: 00 PM the testing personnel confirmed that there were no initial evaluations for three of the six testing personnel listed on the CMS-209.
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 review of the procedure manual and interview with the testing person, the laboratory director failed to specify in writing, the responsibilities and duties of each person engaged in the performance of the pre-analytic, analytic, and post analytic phases of testing, that identifies which examination and procedure each individual is authorized to perform, and whether supervisory or director review is required prior to reporting patient test results. Findings: During the survey on 10/12/18 at 2:00 PM the testing person confirmed that the laboratory's procedure manual did not specify in writing the duties and responsibilities of the laboratory director, clinical consultant, technical consultant, and testing personnel.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with the testing personnel, the laboratory director acting as the technical consultant failed to ensure scientific oversight of the laboratory (D6036); failed to establish acceptable parameters for ensuring that analytical performance standards were maintained throughout the entire testing process (D6042); failed to evaluate the competency of the testing personnel by reviewing the laboratory records (D6049); and failed to ensure that all testing personnel received an annual competency review (D6054).
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the testing personnel, the laboratory director (LD) acting as the technical consultant (TC) failed to be responsible for the oversight of the laboratory. Findings: 1. According to the testing person in charge of the laboratory the LD/TC listed on the CLIA certificate does not document the review of the quality assurance record. The testing person stated that the LD's son reviews the data with the LD but the LD's son is the one who signs the review. 2. The "Medonic Weekly QC Sign Off" worksheets for July 2017 through

	October 5, 2018 were reviewed. There were four worksheets. The first worksheet in the book started with "09/10 - 09/14" and ended with "10/01 - 10/05", no year was recorded on any of the entries. The second worksheet in the book started with "04/9 /18 - 04/14/18" and ended with "9/4 - 9/8", no year was recorded on 13 of the 22 weeks listed. The third worksheet in the book started with "Nov 6th - 10th" and ended with Medonic down "3-8, 4-3-18", no year was recorded on 19 of the 21 weeks listed. The fourth worksheet in the book started with "July week 2" and ended with "October week 4 (10-30 - 11-2)", no year was recorded on any of the entries. 3. The four "Medonic Weekly QC Sign Off" worksheets that were reviewed included four different looking signatures. The LD and the LD's son have the same initials. It could not be determined who actually reviewed the worksheets since the initials on two of the four worksheets looked nothing like the initials on the other two worksheets. 4. There are no "Medonic Weekly QC Sign Off" worksheets available prior to July 2017. 5. During the survey on 10/12/18 at 2:00 PM the testing personnel confirmed that there were no "Medonic Weekly QC Sign Off" worksheets available prior to July 2017.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on record review and interview with the testing personnel, the technical consultant failed to establish acceptable parameters for ensuring that analytical performance standards were maintained throughout the entire testing process. Cross refer to Tag D6000 for details.
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: I. Based on review of the "control summary reports" for the Medonic hematology analyzer and interview with the testing personnel, the laboratory director acting as the technical consultant failed to ensure that the errors found on the reports were investigated and remedial actions taken. Findings: 1. According to the lead testing person the "control summary report" for the hematology analyzer is printed monthly. The lead testing person highlights all the quality control results that are out of the acceptable limits and provides these to the LD for review. 2. According to the lead testing person when quality control (QC) materials are tested each day they are tested in the capillary mode and the venous mode. The results on the "control summary report" do not differentiate between the capillary mode and the venous mode. 3. Review of the "control summary report" for 05/01/2018 through 05/31/2018 showed

	that the normal control was unacceptable and had to be repeated 2 times on 5/1; 2 times on 5/2; 4 times on 5/3; 2 times on 05/25; and 2 times on 05/30. The "control summary report" showed that the hemoglobin (Hgb) and the red blood cells (RBC) were unacceptable but did not differentiate between capillary and venous QC. 4. Review of the "control summary report" for 05/01/2018 through 05/31/2018 showed that the low control was unacceptable and had to be repeated 2 times on 5/25, and the RBC, Hgb, white blood cell (WBC), and hematocrit (Hct) were unacceptable on 5/11 /18 with no repeat analysis of the QC material. The summary did not differentiate between capillary and venous QC. 5. Review of the "control summary report" for 05 /01/2018 through 05/31/2018 showed that the high control was unacceptable and had to be repeated 4 times on 5/2; 3 times on 5/3; 2 times on 5/7; 3 times on 05/25; 9 times on 5/29; 2 times on 05/30; and 3 times on 05/31. The "control summary report" showed that the Hgb, RBC, Hct, and WBC were all unacceptable 7 different times. The "control summary report" showed that the Hgb, and RBC were both unacceptable 6 different times. The "control summary report" showed that the Hgb, RBC and Hct were all unacceptable 7 different times. The summary did not differentiate between capillary and venous QC. 6. On 05/09 the low and high controls were tested once and the report did not differentiate between the capillary or venous mode. The summary did not show that the normal control was tested that day. 7. On 05/10 only the low control was tested and the report did not differentiate between the capillary or venous mode. The summary did not show that the normal and high controls were tested that day. 8. On 05/11 all three controls were tested and the report did not differentiate between the capillary or venous mode. The RBC, Hgb, WBC, and Hct were all unacceptable on 5/11/18 with no repeat analysis of the QC material. 9. The monthly quality assurance (QA) review for May 2018 did not address the problems identified with the unacceptable QC results. 10. The "Corrective Action Log For Daily Control Procedures" worksheet for May 2018 was reviewed. On 5/10/18 the documentation noted that the Medonic was not working. On 5/14, 5/15, and 5/16 the documentation noted that the Medonic was down and no controls run. On 5/17, 5/18, and 5/21 the documentation noted that the Medonic was down, no controls run, and the samples were sent out. The worksheet did not identify what happened to the samples collected on 5/14, 5/15, and 5/16. 11. During the survey on 10/12/18 at 2:00 PM the testing person confirmed that the monthly QA reviews did not address the problems with the unacceptable QC and the samples that were sent to the reference laboratory for testing. II. Based on review of the proficiency testing (PT) records and interview with the testing personnel, the laboratory director acting as the technical consultant failed to ensure that the written policies and procedures established to define how PT samples were to be rotated and used to evaluate the testing personnel were implemented. Findings: 1. Review of the procedure manual shows that the laboratory submitted a procedure for the rotation of PT samples to evaluate the testing personnel as part of the plan of correction for the recertification survey performed on 11/21 /2016. 2. The laboratory has six testing personnel listed on the "Laboratory Personnel Report (CLIA)" (CMS-209). Review of the PT attestation worksheets showed that 4 of the 6 events were performed by one person and the other 2 of 6 events were performed by the same person. 3. During the survey on 10/12/18 at 2:00 PM the testing person confirmed that the laboratory did not implement the plan of correction and rotate the PT samples among the testing personnel as a tool to evaluate the testing personnel.
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 review of the "Medonic M Series Training Check List" evaluation forms and interview with the testing personnel, the laboratory director acting as the technical consultant failed to ensure that all testing personnel received initial, six- month and annual training by the qualified technical consultant. Findings: 1. The laboratory currently has six testing persons listed on the "Laboratory Personnel Report (CLIA) (CMS-209)." The laboratory director is acting as the technical consultant. 2. The testing personnel evaluation records for 2017 and 2018 were reviewed. Six of the six testing persons had their annual reviews performed and documented by a testing person with a high school diploma or a bachelor's degree that did not include the required science classes and two years' experience working in a laboratory. 3. The training check lists for testing person #1 listed on the CMS-209 showed that training was performed on 04/27/18 and 06/07/18. Each check list requires the documentation of 3 observations and 3 successful assays. The check list requires the trainer to document each of those dates. The dates were not documented on either of the check lists reviewed. 4. The training check lists for testing person #3 listed on the CMS-209 showed that training was performed on 10/01/17, 04/27/18, and 06/07/18. Each check list requires the documentation of 3 observations and 3 successful assays. The check list requires the trainer to document each of those dates. There was only one date documented on one of the three check lists reviewed. 5. The training check lists for testing person #4 listed on the CMS-209 showed that training was performed on 10/18 /17, 04/28/18, and 06/07/18. Each check list requires the documentation of 3 observations and 3 successful assays. The check list requires the trainer to document each of those dates. The dates were not documented on either of the check lists reviewed. 6. There was no training documented on the required check list for testing person #2, #5, and #6 listed on the CMS-209. 7. During the survey on 10/12/2018 at 2: 00 PM the testing personnel confirmed that the annual evaluations for 2017 and 2018 were not performed by the qualified technical consultant and that some of the training was not available.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of the "Daily Log" temperature and humidity worksheets and interview with the testing personnel, the testing personnel did not document the humidity each day of testing. Findings: 1. Review of the "Daily Log" for recording the room and refrigerator temperature and humidity for 2018 showed that the humidity was not being recorded. 2. During the survey on 10/12/18 at 2:00 PM the testing personnel confirmed that the humidity was not being recorded as required by the worksheet.