Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0871860	10/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Emerald Pediatric Clinic	11511 Veterans Memorial Drive # 300, Houston, TX	

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	The laboratory was found out of compliance with the CLIA regulations. Immediate jeopardy findings were identified. The conditions not met were: Fed - D - 2000 - 493.801 - Enrollment And Testing Of Samples Fed - D - 5024 - 493.1215 - Hematology Fed - D - 6000 - 493.1403 - Moderate Complexity Laboratory Director Fed - D - 6063 - 493.1421 - Laboratory Testing Personnel The laboratory director provided a letter via email on 11/1/19 stating that the laboratory will suspend all CBC's until the laboratory is back in compliance.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: 41687 Based on review of the laboratory's records and staff interview, it was revealed the laboratory failed to have documentation of being enrolled in proficiency testing for the specialty of hematology in 2018 and 2019. Findings include: 1. A review of the laboratory's records revealed the laboratory started performing hematology testing on the QBC Star hematology analyzer on 8/21/18. The laboratory performed testing for: WBC (white blood cell), MCHC (Mean Corpuscular Hemoglobin Concentration), HGB (hemoglobin), HCT (hematocrit), PLT (platelet), Granulocyte Count, Granulocyte %, Lymph/Mono Count, Lymph/Mono %. 2. The laboratory was asked to provide documentation of enrollment in proficiency testing for the specialty of

	hematology . No documentation was provided. 3. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 10/30/19) on 10/31/19 at 9:45 a.m. in the conference room, she stated, "The people we purchased the instrument from told us we didn't have to do proficiency testing." This confirmed the above findings.
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 review of the laboratory records, and confirmed in interview, the laboratory failed to retain the instrument printouts for CBC (complete blood count) patient testing performed on the QBC Star hematology analyzer for a minimum of 2 years. Findings were: 1. Random review of patient test records from August to October 2019 revealed 1 of 10 records with no documentation of the instrument printout of the CBC test results. See patient alias list. 2. An interview with the primary testing person on 10 /31/19 at 1005 hours in the break room confirmed the above findings.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of Hematology records, patient test results, observations, and interviews, the laboratory failed to meet applicable requirements in the speciality of hematology as evidence by: 1. The laboratory failed to document the date and time of specimen collection to ensure testing analyzed within 15 minutes. Refer to D5313. 2. The laboratory failed to have a quality control procedure that monitored the accuracy and precision of the QBC Star hematology analyzer. Refer D5447. 3. The laboratory failed to document the name and address of the laboratory location where the CBC (complete blood count) testing was performed or the units of measurement for each of the analytes. Refer to D5805.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory 2018 and 2019 test logs, and confirmed in interview, the facility failed to document the time and date it received specimens. Findings were: 1. Review of the QBC Star System operator's manual (6000-300-000) revealed "the tube should be placed in the QBC Star analyzer

	promptly after filling, mixing, and capping, and no later than 15 minutes after filling with blood." 2. Review of 2018 and 2019 test logs revealed no documentation of the time the facility collects specimens for CBC (complete blood count). Specimen time of collection/receipt into the laboratory is vital information in order to ensure specimens are tested within required storage time frames. 3. An interview with the primary testing person on 10/31/19 at 1005 hours in the break room confirmed the above findings. She was unaware the laboratory was required to document the date and time it received specimens.
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 a review of the laboratory's procedure manual, a review of the laboratory's QBC Star System Operator's Manual, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director signing and approving the laboratory's procedures prior to performing testing. Findings include: 1. The laboratory reported starting testing on the QBC Star hematology analyzer on 8/21 /2018. 2. A review of the laboratory's procedure manual revealed the general laboratory policy was approved and signed by the laboratory director on 1/22/2018 and again on 1/22/2019. 3. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 10/30/19) on 10/31/19 at 10:00 in the laboratory revealed the laboratory uses the QBC Star System Operator's Manual as their policy. A review of the QBC Star System Operator's Manual revealed no documentation of the laboratory director approving, signing, or dating this document prior to the laboratory performing testing. This confirmed the above findings.
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: III. Based on review of the laboratory's test system manuals, laboratory environmental records, and interview of laboratory personnel, the laboratory failed to define acceptable limits for the room temperature for analysis of CBC (complete blood count) on the QBC Star Analyzer. Findings were: 1. A review of the QBC Hematology System Operator manual revealed "venous blood sample may be stored at room temperature 20-25 C for up to 8 hours prior to preparation for the QBC Star tube. Samples that cannot be tested immediately must be refrigerated if the room temperature is above 25 C. Refrigerated samples stored at 2-8 C are stable for up to 8 hours. Bring samples back to room temperature before you prepare QBC Star

	Collection tube" to assure proper cell layering in the QBC blood tubes. 2. A review of the environmental records from 2018-2019 for the laboratory revealed the laboratory failed to document the room temperature. 3. Review of the CMS116 revealed the laboratory performed 1440 hematology testing annually. 4. An interview with primary testing person on 10/30/19) at 10:40 hours in the laboratory confirmed the above findings. 41687 I. Based on a review of the System Operator's Manual for the QBC Star hematology analyzer and staff interview, it was revealed the laboratory failed to monitor laboratory temperature and humidity, ensuring accurate and reliable test system operation, for 14 of 14 months. Findings include: 1. A review of the System Operator's Manual (Document Number: 6000-300-000, revision J) for the QBC Star hematology analyzer (installed in August 2018) under the section titled 'Installation and Setup' revealed the following: "Environmental Specifications Operating Temperature: 16 C - 32 C Operating Humidity: 10% - 95% non-condensing" 2. The laboratory was asked to provide documentation of monitoring the laboratory temperature and humidity. No documentation was provided. 3. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 10/30/19) at 10:40 a.m. in the laboratory, she stated, " Ever since we got the new instrument, we were told we didn't have to do it." This confirmed the above findings. II. Based on a review of the manufacturer's instructions for the QBC Star Tube, surveyor observation of supplies stored in the laboratory, and staff interview, it was revealed the laboratory failed to monitor laboratory temperature, essential for proper storage of reagents, for 14 of 14 months. Findings include: 1. A review of the manufacturer's instructions for the QBC Star Tube (L-001078, Rev. F) under the section titled 'TUBE STORAGE' revealed the following: "Store in a dry cupboard or drawer, at 60 to 90 F (16 to 32 C)." 2. Surveyor observation of the QBC Star Tubes stored in the laboratory on 10/31/19 at 10:40 a.m. revealed 104 individually packaged QBC Star tubes stored in the drawer below the hematology analyzer. 3. The laboratory was asked to provide documentation of monitoring the laboratory temperature and humidity. No documentation was provided. 4. The laboratory reported performing 1440 hematology tests on the QBC Star hematology analyzer annually. A random review of patient test records revealed the following patient's samples were run on the QBC star hematology analyzer without making sure the temperature requirements for the QBC Star Tubes were met: Acc # Collection Date P24303 8/27/2018 21753 8/31/2018 28467 9/19/2018 20637 10/10/2018 25596 11/26 /2018 23811 12/10/2018 25664 12/17/2018 P35972 1/12/2019 26933 2/6/2019 23581 3/9/2019 P35271 3/19/2019 32146 4/3/2019 P37811 5/14/2019 20061 6/18/2019 20015 7/2/2019 27113 8/17/2019 P34743 8/27/2019 25960 9/17/2019 21852 9/18 /2019 28852 10/11/2019 5. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 10/30/19) at 10:40 a.m. in the laboratory, she stated, " Ever since we got the new instrument, we were told we didn't have to do it." This confirmed the above findings. Key: C - degrees Celsius F - degrees Fahrenheit
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 a review of the laboratory's test menu, a review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing verification studies for Complete Blood Count (CBC) testing on the QBC Star hematology analyzer. Findings include: 1. A review of the laboratory's test menu revealed the laboratory started performing Complete Blood Count (CBC) testing on the QBC Star hematology analyzer in August 2018. 2. A review of the laboratory's records revealed the laboratory failed to have documentation of performing verification studies to ensure accurate and reliable test results. The following studies were not performed: a) Accuracy b) Precision c) Reportable range d) Verification of normal patient values 3. The laboratory was asked to provide documentation of performing the required verification studies. No documentation was provided. 4. The laboratory reported performing 1440 hematology tests on the QBC Star hematology analyzer annually. 5. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 10/30/19) on 10/31/19 at 10:50 a.m. in the laboratory stated, "We just started running patients on it. The lab director said the values were within range, so it's ok to use." This confirmed the above findings.
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 a review of the manufacturer's instructions for the QBC Star hematology analyzer, a review of the laboratory's policies, and staff interview, it was revealed the laboratory failed to have documentation of performing all required maintenance. Findings include: 1. A review of the manufacturer's instructions for the QBC Star hematology analyzer (document number: 6000-300-000, revision J) under the section titled 'Maintenance', revealed the following maintenance is required by the manufacturer: a) Cleaning - "You should occasionally wipe interior and exterior surfaces of the QBC Star instrument with a damp cloth." b) Tri-Level Quality Control Label -"Routine checking and cleaning of the tri-level quality control label before use of the system will decrease the likelihood of system error due to debris on the label surface." 2. A review of the general laboratory policy under the section titled, 'V. Preventive Maintenance", revealed the following: "All instruments used in moderate complexity testing must be maintained as indicated by the manufacturer's instructions. Preventive maintenance must be performed and documented according to manufacturer's specifications." 3. Further review of the laboratory's general laboratory policy under the section titled, 'V. Preventive Maintenance", revealed the laboratory failed to establish the time frames of 'occasionally' and 'routine' as indicated in the above maintenance activities for the QBC Star hematology analyzer. 4. The laboratory was asked to provide documentation of the missing maintenance being performed. No documentation was provided. 5. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 10/30/19) on 10/31/19 at 10: 45 in the laboratory, she stated, "I clean the outside of the instrument weekly. I do not have a log sheet. That's my fault." This confirmed the above findings.

D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the laboratory's Complete Blood Count (CBC) test records, and staff interview, it was revealed the laboratory failed to have documentation of performing quality control testing on the QBC Star hematology analyzer each day of patient testing . Findings include: 1. A review of the general laboratory policy (signed by the laboratory director on 1/22/2019) under the section titled 'Quality Control' revealed the following: "Quantitative Procedures: At least 2 levels of control will be run each day of testing". 2. A review of the laboratory's CBC test records from 8/21/2018 to 10/31/19 revealed the laboratory performed CBC testing on the following days: 3. The laboratory was asked to provide documentation of performing quality control testing on the QBC Star hematology analyzer each day of patient testing, or of developing an Individualized Quality Control Plan (IQCP) to modify the frequency of control testing. No documentation was provided. 4. The laboratory reported performing 1440 hematology tests on the QBC Star hematology analyzer annually. A random review of patient test records revealed the following patient's samples were run on the QBC star hematology analyzer when there was no quality control testing performed: Acc # Collection Date P24303 8/27/2018 21753 8/31/2018 28467 9/19/2018 20637 10/10/2018 25596 11/26 /2018 23811 12/10/2018 25664 12/17/2018 P35972 1/12/2019 26933 2/6/2019 23581 3/9/2019 P35271 3/19/2019 32146 4/3/2019 P37811 5/14/2019 20061 6/18/2019 20015 7/2/2019 27113 8/17/2019 P34743 8/27/2019 25960 9/17/2019 21852 9/18 /2019 28852 10/11/2019 5. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 10/30/19) on 10/31/19 at 09:45 a. m. in the conference room revealed the laboratory "does not run controls. The instrument does this by itself." This confirms the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: A. Based on review of the patient final reports and confirmed interview, the laboratory failed to document the name and address of the laboratory location where the CBC (complete blood count) testing was performed or the units of measurement

	for each of the analytes. Findings were: 1. Random review of the laboratory results from August 2018 to July 2019 revealed 18 of 18 reports with no documentation of the name and address of the laboratory location where the CBC testing was performed. Date Acc # 08/16/18 26046 08/17/18 21485 10/25/18 25728 11/13/18 31278 11/27/18 25954 12/21/18 31539 01/14/19 22610 01/22/19 20333 02/04/19 P36817 02/07/19 24538 03/19/19 22510 03/27/19 21453 04/01/19 20702 04/08/19 P35845 05/14/19 31229 06/03/19 19386 06/10/19 22978 07/24/19 P38960 2. An interview with the primary testing person on 10/31/19 at 1200 hours in the break room confirmed the above findings. She was unaware the name and address were required on the results. B. Based on review of the patient charts and confirmed interview, the laboratory failed to document the units of measurement for each of the analytes of the CBC (complete blood count) testing on the QBC Star hematology analyzer. Findings were: 1. Review of the laboratory results for the CBC testing on the QBC Star hematology analyzer revealed it tested for the following analytes. Each analyte had the following corresponding units of measurement: Hematocrit: % Hemoglobin: g/dL MCHC: g/dL WBC: x 10^9L Granulocytes: x 10^9L Lymphs + Monos: x 10^9L % Lymphs + Monos: % Platelets: x 10^9L 2. Random review of the laboratory results from the patient charts from August 2018 to July 2019 revealed 18 of 18 reports with no documentation of units of measurement for each analyte for the CBC (complete blood count) testing on the QBC Star hematology analyzer. Date Acc # 08/16/18 26046 08/17/18 21485 10/25/18 25728 11/13/18 31278 11/27/18 25954 12/21/18 31539 01/14/19 22610 01/22/19 20333 02/04/19 P36817 02/07/19 24538 03/19/19 22510 03/27/19 21453 04/01/19 20702 04/08/19 P35845 05/14/19 31229 06/03/19 19386 06/10/19 22978 07/24/19 P38960 2. An interview with the primary testing person on 10/31/19 at 1200 hours in the break room confirmed the above findings.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of the laboratory patient reports and confirmed in interview, the laboratory failed to document reference ranges on their patient electronic records printouts. Findings were: 1. Review of the laboratory results for the CBC testing on the QBC Star hematology analyzer revealed it tested for the following analytes. Hematocrit Hemoglobin MCHC WBC Granulocytes Lymphs + Monos % Lymphs + Monos Platelets 2. Random review of the laboratory results from August 2018 to July 2019 revealed 18 of 18 reports with no documentation of the reference interval for each analyte of the CBC test. Date Acc # 08/16/18 26046 08/17/18 21485 10/25/18 25728 11/13/18 31278 11/27/18 25954 12/21/18 31539 01/14/19 22610 01/22/19 20333 02/04/19 P36817 02/07/19 24538 03/19/19 22510 03/27/19 21453 04/01/19 20702 04/08/19 P35845 05/14/19 31229 06/03/19 19386 06/10/19 22978 07/24/19 P38960 3. An interview with the primary testing person on 10/31/19 at 1200 hours in the break room confirmed the above findings.
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 review of instrument verification records, review of patient final reports, and confirmed in interview, the laboratory director failed to provide overall management and direction of the laboratory. (refer to D6007, D6013, D6015, and D6020)
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on a review of laboratory analytic systems it was revealed that the laboratory director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in Hematology. Refer to D5313, D5447, D5805.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory verification records and confirmed in interview, the laboratory director failed to ensure the laboratory documented complete verification studies for the QBC Star hematology analyzer prior to start of patient testing. Refer to D5421
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, CMS 155 report, and confirmed in interview, the laboratory director failed to ensure the laboratory was enrolled in an approved PT program for testing performed. Findings included: 1. A review of the laboratory's records revealed the laboratory started performing hematology testing on the QBC Star hematology analyzer on 8/21/18. The laboratory performed testing for: WBC (white blood cell), MCHC (Mean Corpuscular Hemoglobin Concentration), HGB (hemoglobin), HCT (hematocrit), PLT (platelet), Granulocyte Count, Granulocyte %, Lymph/Mono Count, Lymph/Mono %. 2. Review of the CMS 155 report revealed no scores for events in 2018 and 2019 for regulated hematology analytes tested by the laboratory. 3. Review of the laboratory records revealed no documentation of the the laboratory enrollment in proficiency testing for the specialty of hematology. 4. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 10/30/19) on 10/31/19 at 9:45 a.m. in the conference room, she stated, "The people we purchased the instrument from told us we didn't have to do proficiency testing." This confirmed the above findings. Word Key: CMS - center for medicare and medicaid services
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) records and confirmed in interview, the laboratory director failed to ensure the laboratory established and maintained a quality control program. Refer to D5447
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel records, and confirmed in interview, the laboratory failed to have documentation of training to qualify them for moderately complex testing for 4 of 4 testing personnel. Refer to D6065
D6065	TESTING PERSONNEL QUALIFICATIONS

	CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel records, and confirmed in interview, the laboratory failed to have documentation of training to qualify 4 of 4 testing personnel for moderately complex testing for CBC (complete blood count) on the QBC Star hematology analyzer. Findings were: 1. A review of personnel records available revealed no documentation of training for 4 of 4 (TP#1 - TP#4) testing personnel. 2. An interview with the primary testing person on 10/31/19 at 1010 hours in the break room confirmed the above findings. She confirmed that all the testing person performed CBC testing on the QBC Star hematology analyzer. CMS - Centers of Medicare and Medicaid Services