Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0957447	10/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
West Texas Pediatrics	5215 96th Street, Lubbock, 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	Based on observations, review of laboratory testing records and personnel records it was determined that the laboratory failed to meet the following conditions of the CLIA regulations found at 493.1 through 493.1780 : 493. 801 Condition: Enrollment and Testing of Samples 493. 1215 Condition: Hematology 493. 1403 Condition: Laboratories performing moderate complexity testing; Laboratory Director 493 .1409 Condition: laboratories performing moderate complexity testing; Technical Consultant 493 .1415 Condition: laboratories performing moderate complexity testing; Clinical Consultant 493. 1421 Condition: Laboratories performing moderate complexity testing; Testing Personnel
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Review of the manufacturer's instructions for use, observations and interview of facility personnel found the laboratory failed to follow the manufacturers instructions when using the cobas Chemstrip 10 UA urine test strips and the One Touch ultra glucose monitor. The findings included: cobas Chemstrip 10 UA urine test strips 1. Review of the cobas Chemstrip UA instructions for use found under the heading Quality control- "For quality control, use commercially available urine controls, or other suitable control material. At a minimum, run a positive and negative control in daily routine. It is also recommended to perform quality control when a new container of strips is opened, when starting a new lot of test strips, when there are questionable results and every 30 days to check the storage conditions of the test strips." 2. Observations made during the tour of the facility found that the laboratory was currently using the cobas Chemstrip UA urine strips lot 29190301 expiration 2019-03-

	31. There were no urine controls available for use in the laboratory. 3. Interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted on October 18, 2018 at 10:25 AM confirmed that the laboratory did not test a positive and negative control each day when using the cobas Chemstrip UA urine strips for patient testing. One Touch ultra glucose monitor 1. Review of the One Touch ultra owners booklet found: on page 13 under the heading Checking the System with Control Solution - "when you should do a control solution test: to practice the test process instead of using blood. When you open a new vial of test strips. Once a week. On page 14 under the heading before you begin: use only One Touch Ultra control solution. Check the expiration date on the control solution vial. Record the discard date (date opened plus 3 months) on the vial label. Do not use after expiration or discard date, whichever comes first." 2. Observations made during the tour the facility found that the laboratory was currently using One Touch Ultra Control Solution Lot 4A2A79 Expiration 11/2006 and One Touch Ultra test strips lot 406-5019 expiration 02/2018. 3. Review of patient test records found that the laboratory tested 25 patient specimens between March 1, 2018 and October 18, 2018 using the expired One Touch ultra test strips. Quality control test records were requested but not provided. 4. Interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted on October 18, 2018 at 9:33 AM confirmed that the expired test strips were the only test strips available for use. She went on to say that the laboratory did not do weekly control solution testing when using the One Touch Ultra glucose monitor.
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: Based on a review of the laboratory testing records, CMS 155 report, and interview of facility personnel it was revealed that the laboratory failed to enroll in a proficiency testing program for each of the each of the specialties and subspecialties for which it seeks certification (Hematology). The findings included: 1. A review of facility records found no documentation of the laboratory being enrolled in or participating in a CMS approved proficiency testing program in 2016, 2017 or 2018 for Hematology. The laboratory started testing patient specimens for Complete Blood Counts using the Sysmex pocH-100 i Hematology analyzer on October 3, 2017. Further review found that verification procedures were initiated November 1, 2016. 2. Review of the CMS 155 report found no proficiency testing scores had been reported to the Centers for Medicare and Medicaid Services (CMS). 3. Interview of testing person one listed on the CMS report 209 Laboratory Personnel Report conducted on October 18, 2018 at 10:05 AM confirmed that the laboratory did not enroll in, or participate in a proficiency testing program for hematology. 4. According to the Annual Test Volume recorded in the CMS 116 application obtained during the inspection, the laboratory performs 1390 hematology tests annually.

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: Review of personnel files, laboratory records, Sysmex pocH- 100i operators manual, quality control records and interview of facility personnel found the laboratory failed to meet the requirements for the specialty of Hematology. Findings Included: 1. The laboratory failed to have a written policy to assess the competency of the technical consultant or testing personnel. (See D5209) 2. Laboratory failed to have procedures available to testing personnel that had been approved signed and dated by the current laboratory director. (See D5407) 3. The laboratory failed to define and monitor the proper temperature and humidity consistent with the manufacturers' instructions for operation of the Sysmex pocH- 100i Hematology Analyzer . (See D5413) 4. The laboratory failed to verify the performance specifications of the Sysmex pocH 100i Hematology Analyzer to ensure it met the manufacturers claims for accuracy, precision, reportable range and establish a reference range suitable for the patient population served by the laboratory. (See D5421) 5. The Laboratory failed to establish a policy defining the frequency of calibration procedures for the Sysmex pocH-100 i hematology analyzer. (See D5403) 6. The Laboratory failed to establish and maintain a quality control program for the Sysmex pocH-100 i hematology analyzer. (See D5441) 7. The laboratory failed to establish written policies and procedures (Quality Assurance) for an ongoing mechanism to monitor, assess and correct problems identified in the Hematology analytic system for testing on the Sysmex pocH 100i Hematology Analyzer before, during and after verification in order to ensure accurate patient results. (See D5791)
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of personnel records, policies and procedures and interview of facility personnel it was revealed that the laboratory failed to have a procedure to assess the competency of consultants, supervisors and testing personnel . Findings included: 1. A review of personnel records found no documentation of competency assessment for the technical consultant or eight of eight testing personnel listed on the CMS 209 Laboratory Personnel Report. 2. Review of policies and procedures found no procedure available to review for assessing the competency of consultants, supervisors or testing personnel. 3. Interview of the testing person one conducted on October 18, 2018 at 9:40 AM confirmed there were no competency assessment records or a procedure for assessing the competency of the technical consultant or testing personnel.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview of facility personnel, the laboratory failed to have a quality assessment program to identify and correct problems in general Lab systems. 1. The laboratory failed to enroll in a proficiency testing program for Hematology. (See D 2000) 2. The laboratory failed to have a procedure in place to assess the competency of all consultants, supervisors and testing personnel. (See D5209)
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 review of the laboratory's policies and procedures and interview of facility personnel, the laboratory failed to have step-by-step instructions for the complete blood count (CBC) testing performed on the Sysmex pocH 100i hematology analyzer. The findings included: 1. The laboratory used the operators guide for the Sysmex pocH 100i hematology analyzer as their own procedure. The operators guide did not define calibration frequency or step-by-step step-by-step performance of the procedure including the interpretation of results, the reportable range for test results has established or verified or control procedure acceptability criteria. Review of the operators guide found on page 5 - 11 under the heading calibration - " calibrate the instrument: if quality control shows repeated deviations in the same direction. If a major component of the instrument has been replaced. Important - calibration does not need to be performed at specific intervals. Follow your internal laboratory regulations for performing calibration. Each sample should be analyzed at least three times. EIGHTCHECK 3WP X-TRA is not suitable for calibration purposes, but for quality

	control instead." A written procedure defining the criteria not specified in the operators guide was requested but not provided. 2. Interview of testing person one conducted on October 18, 2018 and 10:49 AM confirmed that the laboratory did not have a procedure defining calibration frequency, control acceptability criteria or reportable ranges. She went on to confirm that the manufacturer sends calibration materials with every other shipment of quality control material, (approximately every six months) but the lab does not use it.
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: Review of procedures and interview of facility personnel found that the hematology procedures had not been approved signed and dated by the current laboratory director. Findings Included: 1. Review of the operators guide for the Sysmex pocH 100i hematology analyzer found no documentation of approval by the current laboratory director. 2. Interview of Testing Person One on the CMS Report 209 conducted on October 18, 2018 at 10:49 AM confirmed that the current laboratory director had not approved the operators guide for the Sysmex pocH 100i hematology analyzer as the procedure to be used in patient testing. She went on to say that no written policies and procedures were available for review; the laboratory used the manufacturers package inserts and operators guides as its own 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: Review of laboratory records, and interview of the facility personnel found that the laboratory failed to verify the Sysmex pocH 100i hematology analyzer met the manufacturer's performance specifications for accuracy, precision and reportable range, and establish a reference range for its patient populations. Findings included: 1. Review of the provided verification records for the Sysmex pocH 100i hematology analyzer serial number G4741 in use November 1, 2016 found no assessment of accuracy, precision, reportable range or assessment of reference ranges for the patient populations serviced by the laboratory. The laboratory offered a Certificate of Calibration Verification, the poc h-100i implementation checklist and a data sheet for initial certification of preventive maintenance and repair as instrument verification studies. The data presented had not been evaluated to determine if it met the manufacturer's specifications for accuracy, precision and reportable range. 2. Interview of testing person one on the CMS report 209 Laboratory Personnel Report

	conducted on October 18, 2018 at 10:34 AM confirmed that no other verification records were available for review for the Sysmex pocH 100i hematology analyzer. She stated that they did not use a reference range for patients.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of hematology quality control records, patient test records and interview of facility personnel it was revealed that the laboratory failed to have a quality control program that monitored the accuracy and precision of the Sysmex pocH-100i hematology analyzer over time. Findings included: 1. A review of the hematology quality control records for the Sysmex pocH 100-i hematology analyzer from 2017 through 2018 revealed the laboratory failed to print Levy Jennings graphs (used to assess the performance of quality control material over time) for 12 of 12 months between October 2017 and October 2018 , which this analyzer is capable. Without the monthly reports or Levy-Jennings charts the laboratory had no mechanism to monitor the shifts or trends of Quality Control results over time. Further review of the quality control records found that the laboratory used the following lots of quality control material: Lot 725607 - in use between October 2, 2017 to December 20, 2017 Lot 734007 - in use between December 21, 2017 through March 15, 2018 Lot 805907 - in use between March 16, 2018 through June 6, 2018 Lot 814307 - in use between June 7, 2018 through August 30, 2018 Lot 822707 - in use between September 14, 2018 through present 2. Review of the CMS form 116 found that the laboratory recorded an annual test volume of 1390 hematology procedures performed . 3. Interview of testing person one conducted on October 18, 2018 at 10:49 AM confirmed the above findings. She stated that she looked at the quality control data obtained from the Sysmex insight quality control program but was not well-versed in the interpretation of the data. She went on to confirm that the laboratory does not print the data obtained from the Sysmex insight quality control program or the Hematology analyzer itself, nor does the director review the data electronically.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Review of personnel files, laboratory records, Sysmex pocH 100i operators manual, quality control records and interview of facility personnel found the laboratory failed to establish written policies and procedures (Quality Assurance) for an ongoing mechanism to monitor, assess and correct problems identified in the hematology analytic system in order to ensure accurate patient results. . Findings Included: 1. The laboratory failed to have a written policy to assess the competency of the technical consultant or testing personnel. (See D5209) 2. Laboratory failed to have a procedure available to testing personnel that had been approved signed and dated by the current laboratory director. (See D5407) 3. The laboratory failed to define and monitor the proper temperature and humidity consistent with the manufacturers' instructions for operation of the Sysmex pocH 100i Hematology Analyzer . (See D5413) 4. The laboratory failed to verify the performance specifications of the Sysmex pocH 100i Hematology Analyzer to ensure it met the manufacturers claims for accuracy, precision, reportable range and establish a reference range suitable for the patient population served by the laboratory. (See D5421) 5. The Laboratory failed to establish a policy defining the frequency of calibration procedures for the Sysmex po cH100 i hematology analyzer. (See D5403) 6.The Laboratory failed to establish and maintain a quality control program for the Sysmex po cH100 i hematology analyzer. (See D5441)
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: A) Based on review of the operator's guide for the Sysmex pocH 100i hematology analyzer, patient test reports, and interview of facility personnel, the laboratory failed to ensure that reference intervals (normal values) were available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results for four of four patient reports reviewed . Findings included: 1. Review of the Operator's guide for the Sysmex pocH 100i hematology analyzer found on 1-9 "reference intervals (normal population reference intervals) were developed for the pocH 100i using normal individuals. The range for each parameter represents a 95% reference interval. The age range for females was 20 to 79 years, with a mean age of 47. The age range for males was 18 to 83 years, with a mean age of 47. Note: Sysmex recommends that each laboratory establish its own expected reference intervals based upon the laboratory's patient population encountered during daily operation. Expected reference intervals may vary due to the differences in a sex, age, diet, fluid intake, geographic location, etc. the in CCL S document C 28 - 82 "how to define and determine reference intervals in the clinical laboratory; approved guideline" contains guidelines for determining reference values and intervals for quantitative clinical laboratory tests." 2. Review of four of four patient test reports found that patients tested for complete blood counts on the Sysmex pocH 100i hematology analyzer ranged in age from nine months 27 days through 14 years of age. Further review of the four patient test reports found no reference range on the final reports. 3. Interview of testing for someone conducted on October 18, 2018 at 10:49 AM confirmed that the laboratory did not have reference ranges established and available to the providers for the interpretation of CBC results. 2. Review of 2 random final patient reports

	(samples 129713 and 129715) found no reference ranges for Lymph % or MCV on one of two reports. Report for sample 129713 (female) had no reference ranges for Lymph % or MCV 3. Interview of Testing Person 1 conducted on March 7, 2018 at 2: 30 PM confirmed that the reference ranges were missing from the report.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the Sysmex pocH 100i hematology analyzer operator's manual, final patient test records, and interview with facility personnel, the laboratory failed to establish and follow procedures to monitor, assess, and correct problems in the specified in 493.1291. The laboratory did not have a quality assessment program to monitor assess and correct problems in the post-analytic system. The laboratory failed to identify that pediatric reference ranges had not been established and made available to providers for CBC results. (See D5807)
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: The laboratory director failed to provide overall management and direction of the laboratory. 1. The laboratory director failed to ensure that the pocH 100i hematology analyzer had been verified to to ensure that it met the manufacturers specifications for accuracy, precision, reportable range; and establish a reference range appropriate for its pediatric population. (See D 6013) 2. The laboratory director failed to ensure that the laboratory was enrolled in a proficiency testing program for Hematology. (See D6015) 3. The laboratory director failed to ensure that the quality control program for Hematology was established and maintained. (See D6020) 4. The laboratory director failed to ensure that a quality assessment program had been established and maintained. (See D6021) 5. The laboratory director failed to ensure that eight of eight testing personnel met the minimum education requirements for moderate complexity testing. (see D6026) 6. The laboratory director failed to ensure that five of eight testing personnel had received the appropriate training prior to testing patient specimens. (See D6028) 7. The laboratory director failed to ensure that all testing personnel had had been assessed and maintained competency for performing moderately complex procedures in Hematology. (See D6030) 8.The laboratory director failed to specify in writing the responsibilities and duties of each consultant and each person engaged in the performance of patient testing and whether or not supervision was required. (See D6032)
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: Review of the verification records provided for the Sysmex pocH-100i hematology analyzer found that the laboratory director failed to ensure that the assessments for accuracy, precision and other performance characteristics met those as specified by the manufacturer. (See 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 and interview of facility personnel found that the laboratory director failed to ensure the laboratory was enrolled in a proficiency testing program for Hematology . (See D 2000)
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: Review of quality control records and interview of facility personnel found that the laboratory director failed to ensure that the quality control program was established and maintained for hematology . (See D5441)
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of patient test records and staff interview, it was revealed the laboratory director failed to ensure patient test reports contained patient normal ranges to assess patient results (refer to D5807).
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Review of personnel files, laboratory test records, patient test records and interview of facility personnel found that the laboratory director failed to ensure that eight of eight testing personnel performing Hematology testing had the appropriate education and training for performing non waived procedures. (see D 6065 and D 6066)
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: Review of policies and procedures and interview of facility personnel found that the laboratory director failed to ensure that the laboratory had a procedure to assess the competency of all testing personnel, consultants and supervisors; and that they maintained competency. (See D5209)
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: Review of policies and procedures, personal records and interview of facility personnel found that the laboratory director failed to specify in writing , the responsibilities and duties of each consultant and each testing person engaged in patient testing. Findings included: 1. Review of policies and procedures found no written job descriptions or delegation of duties available for review. 2. Review of personnel records found no written job descriptions delegation of duties. 3. Interview of testing person one conducted on October 18, 2018 at 9:37 AM confirmed that the laboratory did not have written Dr. job descriptions or delegation of duties and responsibilities for each consultant, supervisor and testing person engaged in non-waived testing.
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 review of laboratory policies and procedures, quality control records, patient test records, and confirmed in interview with laboratory staff, the technical consultants failed to provide technical and scientific oversight. 1. The technical consultant failed to ensure that verification procedures used to verify the performance specifications for the Sysmex pocH-100i hematology analyzer were adequate to determine accuracy , precision and other performance specifications. (see D 6040) 2. The technical consultant failed to ensure that the laboratory was enrolled in an HHS (Health and Human Services) approved proficiency testing program for Hematology. (see D6041) 4. The technical consultant failed to ensure that a quality control program had been established and maintained to ensure the accuracy and reliability of results obtained when using the pocH-100i hematology analyzer for patient testing . (See D6042) 5. The technical consultant failed to ensure that all testing personnel received the appropriate training for thepocH-100i hematology analyzer . (See D6045) 6. The technical consultant failed to evaluate the competency of testing personnel at least semiannually in the first year of testing and annually thereafter. (See D6053 and D6054)
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)

	The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Review of the verification records provided for the Sysmex pocH-100i hematology analyzer found that the technical consultant failed to ensure that the assessments for accuracy, precision and other performance characteristics met those as specified by the manufacturer. (See D5421)
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of laboratory records and interview of facility personnel, the Technical Consultant failed to ensure the laboratory was enrolled in a proficiency testing program for Hematology. (See D 2000)
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:
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Review of training records and interview of facility personnel found that the technical consultant failed to ensure five of eight testing personnel received training for the pocH 100i hematology analyzer. (See D6066)
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:
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by:
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:
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Reviw of patient test records and interview of facility personnel found that the Clinical Consultant failed to ensure that patient test reports included specific information for interpretation of test results.
D6061	CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1419(c) The clinical consultant must ensure that reports of test results include pertinent information required for specific patient interpretation. This STANDARD is not met as evidenced by: Based on review of patient test records, and interview with facility personnel, the clinical consultant failed to ensure that Hematology test results included pertinent information required for specific patient interpretation. (see D 5807)

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 CMS-209 laboratory personnel report, and staff interview, the laboratory failed to have documentation of education and training to qualify eight of eight testing personnel performing Complete Blood Counts (CBC) using the Sysmex pocH-100i (see D6065 and D6066).
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: Review of laboratory records and interview of facility personnel found that the laboratory had no documentation of education available for review for eight of eight testing personnel listed on the CMS Report 209 performing CBC testing using the Sysmex pocH-100i hematology analyzer. Findings included: 1. Review of personnel records found no documentation of education for testing personnel listed on the CMS report 209 Laboratory Personnel Report. Testing person one - hire date October 5, 2005 testing person two - hire date not provided testing person three - hire date not provided testing person four - hire date not provided testing person five- hire date October 10, 2014 testing person six- hire date July 2, 2018 testing person seven- no hire date provided testing person eight- no hire date provided Education records were requested at 9:33 AM and again at 11:13 AM but not provided. 2. Interview of testing person one conducted on October 18, 2018 at 11:13 AM confirmed that education records were not available for eight of eight testing personnel listed on the CMS report 209 laboratory personnel report.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

	This STANDARD is not met as evidenced by: Review of laboratory records and interview of facility personnel found that five of eight testing personnel listed on the CMS Report 209 had no documentation of training prior to testing patient specimens using the Sysmex pocH-100i hematology analyzer. Findings included: 1. Review of laboratory records found no documentation of training for three of eight testing personnel listed on the CMS Report 209. Training records were requested but not provided for testing persons three, four, five, six and seven. 2. Interview of testing one conducted on October 18, 2018 at 9:40 AM confirmed that no training records were available for review for the five testing personnel listed above.