Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2134272	01/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Check Point Urgent Care Of Crowley, Llc	753 Odd Fellows Rd,Suite F, Crowley, LA	

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	AN INITIAL CERTIFICATION SURVEY was performed at Xpressmed Urgent Care of Crowley, LLC - CLIA # 19D2134272 on January 25, 2018. Xpressmed Urgent Care of Crowley was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1215 CONDITION: Hematology. 42 CFR 493.1403 CONDITION: Laboratory Director performing moderate complexity testing. 42 CFR 493.1409 CONDITION: Technical Consultant. 42 CFR 493.1421 CONDITION: 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: Based on observation, record review and interview with personnel, the laboratory failed to follow the manufacturer's storage requirements for calibration, quality control and verification samples for waived chemistry testing. Findings: 1. Observation by the surveyor on January 25, 2018 found calibration, and quality control samples for waived chemistry testing being stored in the freezer compartment of a Table Top Galanz Refrigerator/Freezer. Further observation found the laboratory failed to monitor the temperature of the Freezer portion of the Galanz Refrigerator /Freezer. The following items were noted as being stored in the Freezer of the Galanz Refrigerator/Freezer without monitoring the temperature of the freezer: a) Biosource Technology BRT Liquid Assayed Chemistry and Lipid Controls: six (6) Vials of Level 1 and six Vials of Level 2; lot number 1703007 with an expiration date of 2018 /06. NOTE: The manufacturers required storage temperature located on the outside of the box stated the items are to be stores at - 15 degrees Celsius or colder. b) Alere Triage Total 5 Controls: three (3) Vials of Level 1 - lot number C3350A with an

	expiration date of 2018/07/11 and, four (4) Vials of Level 2 - lot number C3365A with an expiration date of 2018/07/11. NOTE: The manufacturers required storage temperature located on the outside of the box stated the items are to be stores at - 20 degrees Celsius or colder. c) Alere Triage Total 5 Calibration Verification Material: nine (9) Vials - lot number 407521 with an expiration date of 2018/05/17. NOTE: The manufacturers required storage temperature located on the outside of the box stated the items are to be stores at - 20 degrees Celsius or colder. 2. Observation by the surveyor on January 25, 2018 found the following quality control and verification samples for waived testing being stored in the Refrigerator portion of the table top Galanz Refrigerator/Freezer. The following items were being stored between 2 - 8 degrees Celsius which was outside the manufacturers requirements. a) Alere Triage BNP Controls: five (5) Vials of Level 1 - lot number C3340A with an expiration date of 2018/08/14 and, five (5) Vials of Level 2 - lot number C3337A with an expiration date of 2018/07/17. NOTE: The manufacturers required storage temperature located on the outside of the box stated the items are to be stores at - 20 degrees Celsius or colder. b) Biosource Technology BRT Controls: six (6) Vials of level 1 and six (6) Vials of Level 2 - lot number 1705005 with an expiration date of 2018/09. NOTE: The manufacturers required storage temperature located on the outside of the box stated the items are to be stores at - 15 degrees Celsius or colder. c) Biosource Technology BRT Verification Samples: three (3) Vials of each level 1, 2 and 3 - lot number 1708005 with an expiration date of 2018/12. NOTE: The manufacturers required storage temperature located on the outside of the box stated the items are to be stores at - 15 degrees Celsius or colder 2. Interview with the Technical Consultant on January 25, 2017 confirmed the laboratory failed to store calibration, quality control and verification samples according to the manufacturer.
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 a record review, and interview with personnel, the laboratory failed to ensure the quality of testing in the specialty of Hematology. Findings: 1. The laboratory failed to maintain a complete policy and procedure manual. Refer to D5403. 2. The laboratory failed to verify performance specifications for the Sysmex XP-300 Hematology Analyzer for Complete Blood Cell (CBC) testing. Refer to D5421. 3. The laboratory failed to document the weekly maintenance on the Sysmex XP-300 Hematology Analyzer for two (2) of eight (8) weeks reviewed. Refer to D5429. 4. The laboratory failed to establish means and ranges for Quality Control (QC) material used for the Sysmex XP-300 Hematology Analyzer as required by the manufacturer for six (6) of six (6) lots of quality control material. Refer to D5469. 5. The laboratory failed to establish written policies and procedures in place to monitor, assess, and correct problems identified with the Hematology Systems. Please refer to D5791.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints

	and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel the laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to have written policies and procedure for addressing complaints and problems reported to the laboratory. The policy should include a detailed procedure on how to address, document and handle complaints or problems reported to the laboratory. 2. Interview with the Technical Consultant on January 25, 2018 confirmed the laboratory failed to have a complete policy and procedure manual.
D5207	COMMUNICATIONS CFR(s): 493.1234 The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel the laboratory failed to have a system in place to ensure that it identifies and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to have written policies and procedure to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. 2. Interview with the Technical Consultant on January 25, 2018 confirmed the laboratory failed to have a complete policy and procedure manual.
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 Laboratory's Policy and Procedures and interview with personnel, the laboratory failed to maintain a complete policy and procedure manual. Findings: 1. Review of the policy and procedure manual revealed the laboratory did not have detailed policies and procedures for the following: a) Test Requisitions: what information is needed to be able to collect, process and report laboratory results. b) Proficiency Testing: how to handle failures and what corrective action to take when the laboratory fails two (2) out of three (3) events for the same analyte or specialty /subspecialty for the first and second failures. c) Performance Specifications to include: * Instructions for testing personnel of what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. * Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. * How to handle when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. d) Establishment of written policies and procedures for Quality Control (QC) which include: * What QC testing will be performed, when it will be performed, and how often it will be performed. * Establishment of mean and ranges for QC materials to include but not limited to: How to establish ranges for QC materials and/or verification of QC material *What corrective action to take when calibration and/or control results fail to meet laboratory's criteria for acceptability e) Description of the course of action to take if a test system becomes inoperable. f) Pertinent literature references to support all policies and procedures. 2. Interview with the Technical Consultant on January 25, 2018 confirmed the laboratory policy and procedure manual was incomplete.
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 observation, record review and interview with personnel, the laboratory failed to verify performance specifications for the Sysmex XP-300 Hematology Analyzer for Complete Blood Cell (CBC) testing. Findings: 1. Observation by surveyor on January 25, 2018 revealed the laboratory maintained the Sysmex XP-300 Hematology Analyzer for CBC testing which includes: White Blood Cells (WBC), Red Blood Cells (RBC), Hemoglobin (HGB), Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Red Blood Cell Distribution Width (RDW), Platelets (PLT), Lymphocytes % (LYMPH %), Neutrophils % (NEUT %), Mixed %,

	Lymphocytes # (LYMPH #), Neutrophils # (NEUT #), and Mixed #. 2. Review of the Sysmex Field Representative's documentation performed on July 27, 2017 revealed studies for calibration, correlation, reportable range and carry over. Further review of the Sysmex Field Representatives documentation revealed a note that stated the instrument "needed to be updated by the customer if needed per local regulatory requirements." 3. Interview with the Technical Consultant on January 25, 2018 confirmed the data was performed by the Sysmex Field Representative and the laboratory did not verify the manufacturer's performance specifications to demonstrate that the laboratory could get comparable studies to the manufacturer for accuracy, precision, reportable and reference ranges. 4. Review of the Task 1 and 3 Form submitted to the surveyor on January 25, 2018 revealed the laboratory performed an annual volume of 120 - WBC, 120 - RBC, 120 - HGB, 120 - HCT, 120 - MCV, 120 - MCH, 120 - MCHC, 120 - RDW, 120 - PLT, 120 - LYMPH %, 120 - NEUT %, 120 - Mixed %, 120 - LMPH #, 120 - NEUT #, and 120 - Mixed #.
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 observation, record review and interview with personnel, the laboratory failed to document the weekly maintenance on the Sysmex XP-300 Hematology Analyzer for two (2) of eight (8) weeks reviewed. Findings: 1. Observation by the surveyor on January 25, 2018 revealed the laboratory utilized a Sysmex XP-300 Hematology Analyzer for Complete Blood Count (CBC) testing. 2. Review of the Sysmex XP-300 Hematology Analyzer Maintenance Logs from December 1, 2017 through January 25, 2018 revealed the laboratory is to "Clean SRV Tray" on a weekly basis. Further review of the Maintenance Logs reveled the laboratory failed to document the performance of cleaning the SRV Trays for the weeks of January 2, 2018 and the week of January 18, 2018. 3. Interview with the Technical Consultant on January 25, 2018 confirmed the laboratory did not clean the SRV Trays for the two (2) weeks cited above.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish means and ranges for Quality Control (QC) material used for the Sysmex XP-300 Hematology Analyzer as required by the manufacturer for six (6) of six (6) lots of quality control material. Findings: 1. Observation by the surveyor on January 25, 2018 revealed the laboratory utilizes the Sysmex XP-300 Hematology Analyzer for Complete Blood Cell (CBC) testing. Further observation by the surveyor noted the laboratory utilized Sysmex Eight-Check - 3WP X-TRA Quality Control for Complete Blood Count (CBC) testing. 2. Review of the Sysmex Eight-Check - 3WP X-TRA quality control package insert revealed "The expected ranges listed on the assay sheet represent estimates of inter-laboratory variation for each parameter. These expected ranges should not be used as QC file limits. Inter-laboratory variation is usually accounted for by analyzer calibration, maintenance and operating technique". 3. Review of the Laboratory's Policy and Procedure Manual revealed testing personnel are to verify Quality Control material by running the quality control material twice a day for five (5) days to assure the values obtained are within the manufacturer's ranges. Further review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to establish written policies for the establishment of means and ranges for CBC testing performed on the Sysmex XP-300 Hematology Analyzer. 4. Review of Quality Control Records revealed the laboratory verified the manufacturer's ranges for the following six (6) lots of Sysmex Eight-Check - 3WP X-TRA quality control material: a) Placed into use on November 1, 2017: lots 71710710, 71710711 and 71710712. b) Placed into use on January 5, 2018: lots 73390711, 73390710, and 73390712. 5. Interview with the Technical Consultant on January 25, 2018 confirmed the laboratory was verifying the manufacturer's ranges and did not establish mean and ranges for the six (6) lots of Sysmex Eight-Check - 3WP X-TRA quality control material.
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: Based on observation, record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. A review of patient test records and quality control records indicated problems found in Hematology as follows: a) The laboratory failed to maintain a complete policy and procedure manual. Refer to D5403. b) The laboratory failed to verify performance specifications for the Sysmex XP-300 Hematology Analyzer for Complete Blood Cell (CBC) testing. Refer to D5421. c) The laboratory failed to document the weekly maintenance on the Sysmex XP-300 Hematology Analyzer for two (2) of eight (8) weeks reviewed. Refer to D5429. d) The laboratory failed to establish means and ranges for Quality Control (QC) material used for the Sysmex XP-300 Hematology Analyzer as required by the manufacturer for six (6) of six (6) lots of quality control material. Refer to D5469. 2. The laboratory had a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory. However, the laboratory failed to include monitors that

	would correct the issues cited above. 3. Interview with the Technical Consultant on January 25, 2017 confirmed the laboratory was unaware of the issues cited above, and failed to monitor all phases of Hematology testing to assure that testing is being performed accurately and reliably.
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: Based on record review and interview with personnel, the laboratory failed to include the name and address of the laboratory location where testing was performed on test reports for eleven (11) of eleven (11) patients reviewed. Findings: 1. Review of random selection of Patient Hematology Final Test Reports from December 7, 2017 through January 12, 2018 revealed the laboratory failed to include the name and address of the laboratory on patient final test reports for the following eleven (11) patients: On December 7, 2017 Patient 11. On December 8, 2017 Patient 10. On December 11, 2017 Patient 9. On December 27, 2017 Patient 8. On December 31, 2017 Patient 7. On January 2, 2018 Patients 5 and 6. On January 5, 2018 Patient 1. On January 10, 2018 Patient 2. On January 11, 2018 Patient 3. On January 12, 2018 Patient 4. 2. Interview with the Technical Consultant on January 25, 2018 confirmed the name and address of the laboratory failed to be on Patient Hematology Final Test Reports.
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 observation, record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that verification procedures are performed to determine accuracy, precision, reportable and reference ranges for the Sysmex XP-300 Hematology Analyzer for Complete Blood Count (CBC) testing. Refer to D6013. 2. The Laboratory Director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Refer to D6020. 3. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D6021. 4. The Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical

	performance. Refer to D6023. 5. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6031.
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 observations, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that verification procedures are performed to determine accuracy, precision, reportable and reference ranges for the Sysmex XP-300 Hematology Analyzer for Complete Blood Count (CBC) testing. Refer to D5421.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to verify performance specifications for the Sysmex XP-300 Hematology Analyzer for Complete Blood Cell (CBC) testing. Refer to D5421. 2. The laboratory failed to establish means and ranges for Quality Control (QC) material used for the Sysmex XP-300 Hematology Analyzer as required by the manufacturer for six (6) of six (6) lots of quality control material. Refer to D5469.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Findings: 1. A review of patient test records and quality control records indicated problems as follows: a) The laboratory failed to maintain a complete policy and procedure manual. Refer to D5403. b) The laboratory failed to verify performance specifications for the Sysmex XP-300 Hematology Analyzer for Complete Blood Cell (CBC) testing. Refer to D5421. c) The laboratory failed to document the weekly maintenance on the Sysmex XP-300 Hematology Analyzer for two (2) of eight (8) weeks reviewed. Refer to D5429. d) The laboratory failed to establish means and ranges for Quality Control (QC) material used for the Sysmex XP-300 Hematology Analyzer as required by the manufacturer for six (6) of six (6) lots of quality control material. Refer to D5469. e) The laboratory failed to include the name and address of the laboratory location where testing was performed on test reports for eleven (11) of eleven (11) patients reviewed. Refer to D5805. 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory establish a Quality Assurance Plan that covered all phases of testing; however the laboratory failed to identify and correct the problems cited above. Refer to 5791. 3. Interview with the Technical Consultant on January 25, 2018 confirmed the laboratory failed to identify the deficiency cited above.
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 manufacturer's instructions, instrument maintenance records and interview with laboratory personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Findings: 1. The laboratory failed to document the weekly maintenance on the Sysmex XP-300 Hematology Analyzer for two (2) of eight (8) weeks reviewed. Refer to D5429. 2. Interview with the Technical Consultant on January 25, 2018 confirmed the above findings.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

	This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. Review of the policy and procedure manual revealed the laboratory did not have detailed policies and procedures for the following: a) Test Requisitions: what information is needed to be able to collect, process and report laboratory results. b) Proficiency Testing: how to handle failures and what corrective action to take when the laboratory fails two (2) out of three (3) events for the same analyte or specialty/subspecialty for the first and second failures. c) Performance Specifications to include: * Instructions for testing personnel of what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. * Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. * How to handle when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. d) Establishment of written policies and procedures for Quality Control (QC) which include: * What QC testing will be performed, when it will be performed, and how often it will be performed. * Establishment of mean and ranges for QC materials to include but not limited to: How to establish ranges for QC materials and/or verification of QC material *What corrective action to take when calibration and/or control results fail to meet laboratory's criteria for acceptability e) Description of the course of action to take if a test system becomes inoperable. f) Pertinent literature references to support all policies and procedures. 2. Interview with the Technical Consultant on January 25, 2018 confirmed the laboratory policy and procedure manual was incomplete.
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 observation, record review, and interview with personnel, the Technical Consultants failed to meet the qualifications and provide technical oversight of the laboratory. Findings: 1. The Technical Consultant failed to meet the qualifications for a Technical Consultant of moderate complexity testing. Refer to D6035. 2. The Technical Consultant failed to provide technical and scientific oversight for the laboratory. Refer to D6036.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of

	Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Technical Consultant failed to meet the qualifications for a Technical Consultant of moderate complexity testing. Findings: 1. Review of personnel records revealed the laboratory maintained a copy of a current license; however the laboratory failed to have a copy of the Technical Consultant's education with a minimum requirement of a bachelors degree in a chemical, physical or biological science or medical technology from an accredited institution, and a copy of his Curriculum Vitae (CV). 2. Interview with the Technical Consultant on January 25 2018 confirmed the laboratory did not retain the above qualifications for the Technical Consultant.
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 observation, record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight for the laboratory. Findings: 1. Review of the FORM CMS 209 submitted to the surveyor on January 25, 2018 revealed that personnel 2 fulfilled the duties for Technical Consultant. 2. Observation, record review and interview with personnel revealed the Technical Consultant failed to address the following problems identified in the laboratory: a) The laboratory failed to maintain a complete policy and procedure manual. Refer to

	D5403. b) The laboratory failed to verify performance specifications for the Sysmex XP-300 Hematology Analyzer for Complete Blood Cell (CBC) testing. Refer to D5421. c) The laboratory failed to document the weekly maintenance on the Sysmex XP-300 Hematology Analyzer for two (2) of eight (8) weeks reviewed. Refer to D5429. d) The laboratory failed to establish means and ranges for Quality Control (QC) material used for the Sysmex XP-300 Hematology Analyzer as required by the manufacturer for six (6) of six (6) lots of quality control material. Refer to D5469. e) The laboratory failed to establish written policies and procedures in place to monitor, assess, and correct problems identified with the Hematology Systems. Please refer to D5791. f) The laboratory failed to include the name and address of the laboratory location where testing was performed on test reports for eleven (11) of eleven (11) patients reviewed. Refer to D5805. 2. Interview with the Technical Consultant on January 25, 2018 confirmed he failed to identify the deficiency cited above.
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 record review and interview with laboratory personnel, the laboratory failed to ensure testing personnel met the qualifications of education and licensure to perform moderate complexity testing. Findings: 1) The laboratory failed to have evidence that testing personnel performing non-waived testing met the educational qualifications for performing high complexity testing, for two (2) of four (4) testing persons. Refer to tag D6065. 2) Interview with the Technical Consultant on January 25, 2017 confirmed the above findings
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 record review and interview with personnel, the laboratory failed to provide documentation that testing personnel met the educational qualifications for performing moderate complexity testing for two (2) of four (4) testing personnel. Findings: 1. Review of personnel records on January 25, 2018 revealed the laboratory failed to maintain documentation of at least a High School Diploma or equivalent for

	moderate complexity laboratory testing for Personnel 4, and 6. 2. Interview with the Technical Consultant on January 25, 2018 confirmed the laboratory failed to maintain documentation of the highest level of education for personnel 4, and 6 as indicated above.