Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0684375	06/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Union Carbide Corp-Taft Medical Dept	355 Highway 3142, Building 632, Hahnville, 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 Survey was performed at Union Carbide Corp-Taft Medical Department on June 13, 2019. Union Carbide Corp-Taft Medical Department was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1215 CONDITION: Hematology 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing, Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories performing moderate complexity testing, Technical Consultant 42 CFR 493.1417 CONDITION: Laboratories performing moderate complexity testing, Clinical Consultant
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 observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing for the specialty of Hematology. Findings: 1. The laboratory failed to ensure written policies and procedures to assess competency for the Clinical Consultant were complete. Refer to D5209 I. 2. The laboratory failed to establish written policies and procedures to assess competency for testing personnel. Refer to D5209 II. 3. The laboratory failed to establish a laboratory policy and procedure manual. Refer to D5401. 4. The laboratory failed to have a complete policy and procedure manual. Refer to D5403. 5. The laboratory failed to document the temperature of the collection area where laboratory supplies are stored per manufacturer requirements. Refer to D5413. 6. The laboratory failed to ensure blood collection supplies have not exceeded their expiration date. Refer to D5417. 7. The laboratory failed to have complete performance specification verification studies for the Beckman Coulter ACT diff Hematology analyzer. Refer to D5421. 8. The

	laboratory failed to ensure quality control for Complete Blood Counts (CBC) met acceptability criteria per laboratory policy prior to patient testing. Refer to D5481. 9. Tthe laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to 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: I. Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the Clinical Consultant were complete. Findings: 1. Review of the laboratory's records revealed the laboratory did not have a policy for competency assessment of the Clinical Consultant, including frequency of performance. 3. Review of personnel records for the Clinical Consultant revealed a competency assessment for duties as Clinical Consultant was not performed. 3. In interview on June 12, 2019, the Laboratory Director stated she did not perform a competency assessment for the Clinical Consultant. The Laboratory Director stated she did not have competency assessment policies. II. Based on record review and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's records revealed the laboratory did not have written policies and procedures for competency that included the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on June 12, 2019, the Laboratory Director stated she did not have policies for personnel competency. The Laboratory Director further stated she was unsure of what was needed since she is the only personnel that performs the Hematology testing.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish a laboratory policy and procedure manual. Findings: 1. Review of the

	laboratory's documents and records revealed the laboratory did not have written polices and procedures that included: a) Corrective action: to address failures that may occur in the preanalytic, analytic, and post analytic systems b) Performance specification: detailed procedures for performing accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference range studies, acceptability criteria for studies, and actions to take when data from the studies fail to meet acceptability criteria c) Retention requirements d) Proficiency Testing including requirements for handling, testing, reporting, and actions for failures e) Complaint Investigations 2. In interview on June 13, 2019 at 9: 51 am, the Laboratory Director stated the laboratory does not have a general policy and procedure manual. The Laboratory Director confirmed the only policy provided to surveyor was the procedure for CBC testing.
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 record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's documents and records revealed the laboratory did not have a written procedure manual that included the following when applicable to the test procedure: a) Detailed policies and procedures for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242 b) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing c) Quality Control to include: Type, who is to monitor, identification of shifts/trends, acceptability criteria, and verification of new lot numbers of quality control material. d) Reportable range for test results for the test system as established or verified e) Corrective actions to take when calibration or control results fail to meet the laboratory's criteria for acceptability; including when to contact service and perform patient assessments f) Limitations in the test methodology; including interfering substances g) Reference intervals (normal values) h) Pertinent literature references i) Laboratory's system for entering results in the patient record and reporting patient test results j) Course of action if test system becomes inoperable 2. In interview on June

	13, 2019 at 9:51 am, the Laboratory Director stated the laboratory does not have a general policy and procedure manual.
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: Based on observation, record review and interview with personnel, the laboratory failed to document the temperature of the collection area where laboratory supplies are stored per manufacturer requirements. Findings: 1. Observation by the surveyor during the laboratory tour June 12, 2019 revealed the laboratory had thermometers located in the collection area where sample collection supplies are stored; however, the laboratory did not document the temperature. 2. In interview on June 12, 2019 at 9: 38 am, the Laboratory Director stated she does not document the temperature of the collection room. 3. Further observation by surveyor during the laboratory tour on June 12, 2019 revealed the following items were stored in the collection room: a) BD Vacutainer Urine Analysis Preservative Tubes, Lot # 8215649, Quantity: approximately 180 tubes b) BD Vacutainer K2 EDTA blood collection tubes, Lot # 9036764, Quantity: 100 tubes c) BD Vacutainer SST blood collection tubes, Lot # 8347963, Quantity: approximately eighty (80) tubes d) BD Vacutainer Lithium Heparin blood collection tubes, Lot # 830287, Quantity: approximately forty (40) tubes 4. Review of the BD Vacutainer manufacturer requirements revealed a storage requirement of 4-25 degrees Celsius.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the laboratory failed to ensure blood collection supplies have not exceeded their expiration date. Findings: 1. Observation by surveyor during laboratory tour on June 12, 2019 revealed the following expired items located in the collection room: a) BD Vacutainer Trace Element K2EDTA blood collection tubes, Lot # 7157861, Expiration date: 2018-06-30, Quantity: ten (10) tubes b) BD Vacutainer Eclipse Blood Collection Needles, Lot # 7064857, Expiration date: 2012-03, Quantity: one (1) box 2. In interview on June 12, 2019, the Laboratory Director stated she did not use the blood collection tubes. The Laboratory Director confirmed the identified items were expired.
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 have complete performance specification verification studies for the Beckman Coulter ACT diff Hematology analyzer. Findings: 1. Observation by surveyor during the laboratory tour on June 12, 2019 revealed the laboratory utilizes the Beckman Coulter ACT diff analyzer for Complete Blood Counts (CBC) testing. 2. Review of the laboratory's records revealed the laboratory did not have a policy for performance verification studies for new instruments. 3. Review of the laboratory's performance verification studies revealed the following information was not included: a) Accuracy: raw data for comparison study with acceptability criteria b) Precision: raw data to include day-to-day, run-to-run, within-run, acceptability criteria c) Reference Range d) Laboratory Director approval/signature 4. In interview on June 12, 2019 approximately 11:00 am, the Laboratory Director stated the Hematology instrument was installed November 2017. The Laboratory Director stated comparison studies performed November 2017 through February 2018 with Lab Corp were part of the accuracy study. At 1:24 pm, The Laboratory Director stated she did not include the data for the comparison studies in the validation binder. The Laboratory Director stated the "Reproducibility Results" from November 7, 2017 and August 14, 2018 were used for precision study. The Laboratory Director confirmed the data did not include day-to-day data with acceptability criteria. The Laboratory Director stated the laboratory utilizes Lab Corp's reference ranges. The Laboratory Director stated the laboratory did not perform their own reference range studies. The Laboratory Director stated she did not where Lab Corp obtained their reference ranges from. The Laboratory Director confirmed the validation studies did not include acceptability criteria and her signature/approval.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure quality control for Complete Blood Counts (CBC) met acceptability criteria per laboratory policy prior to patient testing. Findings: 1. Observation by surveyor during laboratory tour on June 12, 2019 revealed the laboratory utilizes the Beckman Coulter ACT diff instrument for Complete Blood Count (CBC) testing. 2. Review of the laboratory's "Procedure for CBC testing on the Coulter ACT diff" procedure revealed "Controls must be run each day before patient samples can be reported. If at least 2 of

	the 3 levels of control are in range for each analyte, proceed with running patient samples." 3. Review of the "Coulter 4C-ES Cell Control" insert under "Assigned Values and Expected Ranges" revealed "whether you use the Beckman Coulter Assigned Value or your own laboratory mean, the instrument is considered well maintained and operating correctly if: > 95% of the recovered values fall within the EXPECTED RANGE of the Beckman Coulter Assigned Value. Recovered values do not trend OUTSIDE the EXPECTED RANGE." 4. Review of QC records for February 26, 2019 through May 2019 revealed the laboratory tested the following two (2) patient samples prior to two (2) acceptable levels of QC being tested per laboratory policy: March 27, 2019: Low control (lot # 069100) acceptable at 6:18 am, Normal control (lot # 079100) acceptable at 14:23, Patient 388488 tested at 6:57 am April 10, 2019: Low control (lot # 069100) acceptable at 5:45 am, Normal control (lot # 079100) acceptable at 8:30 am, Patient 580676 tested at 7:36 am 5. In interview on June 12 , 2019, the Laboratory Director stated she held the patient results until two (2) levels of QC were within normal limits. The Laboratory Director stated she thought since it was a QC issue and not an instrument issue that the patient results were acceptable. The Laboratory Director stated she did not perform corrective action for the identified patients.
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 failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. The laboratory failed to ensure written policies and procedures to assess competency for the Clinical Consultant were complete. Refer to D5209 I. 2. The laboratory failed to establish written policies and procedures to assess competency for testing personnel. Refer to D5209 II. 3. The laboratory failed to establish a laboratory policy and procedure manual. Refer to D5401. 4. The laboratory failed to have a complete policy and procedure manual. Refer to D5403. 5. The laboratory failed to document the temperature of the collection area where laboratory supplies are stored per manufacturer requirements. Refer to D5413. 6. The laboratory failed to ensure blood collection supplies have not exceeded their expiration date. Refer to D5417. 7. The laboratory failed to have complete performance specification verification studies for the Beckman Coulter ACT diff Hematology analyzer. Refer to D5421. 8. The laboratory failed to ensure quality control for Complete Blood Counts (CBC) met acceptability criteria per laboratory policy prior to patient testing. Refer to D5481.
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 where testing was performed. Findings: 1. Review of random selection of patient final test reports revealed the laboratory did not include the laboratory's name and address on the final reports. 2. In interview on June 12, 2019, the Laboratory Director stated the name and address of the laboratory was not included on the final reports. 3. Review of the laboratory's Task 1 and 3 form revealed the laboratory performs 2,500 Complete Blood Counts (CBC) tests annually.
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 complete verification procedures were performed. Refer to D6013. 2. The Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D6014. 3. The Laboratory Director failed to ensure the laboratory was enrolled in a proficiency testing program for Hematology prior to patient testing. Refer to D6015. 4. The Laboratory Director failed to ensure the quality control program was maintained to assure quality laboratory services were provided. Refer to D6020. 5. 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. 6. The Laboratory Director failed to ensure final reports for Complete Blood Counts (CBC) included required pertinent information. Refer to D6026. 7. The Laboratory Director failed to ensure the Clinical Consultant met educational requirements. Refer to D6029. 8. The Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency. Refer to D6030. 9. 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. 10. The Laboratory Director failed to provide written job descriptions for all Laboratory Personnel. Refer to 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: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to document the temperature of the collection area where laboratory supplies are stored per manufacturer requirements. Refer to D5413. 2. The laboratory failed to ensure blood collection supplies have not exceeded their expiration date. Refer to D5417.
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 record review and interview with personnel, the Laboratory Director failed to ensure the laboratory was enrolled in a proficiency testing program for Hematology prior to patient testing. Findings: 1. In interview on June 12, 2019 at 9:20 am, the Laboratory Director stated the laboratory started patient testing for Complete Blood Counts (CBC) on February 26, 2019. 2. Review of the laboratory's records revealed the laboratory did not have documentation of proficiency test performance. 3. In further interview on June 12, 2019 at 10:22 am, the Laboratory Director stated the laboratory enrolled in the American Proficiency Institute's proficiency testing program in April 2019. The Laboratory Director stated the laboratory missed the first event.
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 record review and interview with personnel, the Laboratory Director failed to ensure the quality control program was maintained to assure quality laboratory services were provided. Refer to D5481.
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 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. Refer to D5791.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure final reports for Complete Blood Counts (CBC) included required pertinent information. Refer to D5805.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel

	have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the Clinical Consultant met educational requirements. Refer to D6057.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency. Findings: 1. The laboratory failed to ensure written policies and procedures to assess competency for the Clinical Consultant were complete. Refer to D5209 I. 2. The laboratory failed to establish written policies and procedures to assess competency for testing personnel. Refer to D5209 II. 3. The Technical Consultant failed to ensure test performance through testing previously analyzed specimens, internal blind samples, or external proficiency samples was assessed. Refer to D6051.
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. The laboratory failed to establish a laboratory policy and procedure manual. Refer to D5401. 2. The laboratory failed to have a complete policy and procedure manual. Refer to D5403 3. Review of the laboratory's "Procedure for CBC testing on the Coulter ACT diff" procedure revealed the Laboratory Director created the document;

	however, the Clinical Consultant's name was listed under the "Approved By" column. 4. In interview on June 12, 2019, the Laboratory Director confirmed the Clinical Consultant approved the procedure for Complete Blood Count (CBC) testing.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide written job descriptions for all Laboratory Personnel. Findings: 1. Review of the laboratory's records revealed the laboratory did not have a written job description for the Laboratory Director and Clinical Consultant. 2. In interview on June 12, 2019, the Laboratory Director confirmed the laboratory did not have the identified job descriptions.
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 Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight of the laboratory. Refer to D6036. 2. The Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D6040. 3. The Technical Consultant failed to ensure participation in an HHS approved proficiency testing program. Refer to D6041. 4. The Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D6042. 5. The Technical Consultant failed to ensure test performance through testing previously analyzed specimens, internal blind samples, or external proficiency samples was assessed. Refer to D6051.
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 laboratory personnel, the Technical Consultant failed to provide technical and scientific oversight of the laboratory. Findings: 1. The laboratory failed to establish a laboratory policy and procedure manual. Refer to D5401. 2. The laboratory failed to have a complete policy and procedure manual. Refer to D5403. 3. The laboratory failed to document the temperature of the collection area where laboratory supplies are stored per manufacturer requirements. Refer to D5413. 4. The laboratory failed to ensure blood collection supplies have not exceeded their expiration date. Refer to D5417. 5. The laboratory failed to include the name and address where testing was performed. Refer to D5805.
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: Based on observation, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to 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 record review and interview with personnel, the Technical Consultant failed to ensure participation in an HHS approved proficiency testing program. Refer to D6015.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by:

	Based on observation, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5481.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure test performance through testing previously analyzed specimens, internal blind samples, or external proficiency samples was assessed. Findings: 1. In interview on June 12, 2019 at 9:20 am, the Laboratory Director stated the laboratory began patient testing for Complete Blood Counts (CBC) on February 26, 2019. 2. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the Laboratory Director serves as Technical Consultant and Testing Personnel also. 3. Review of the laboratory's records revealed the laboratory did not have documentation of external proficiency sample performance. Refer to D6015. 4. Further review of the laboratory's records revealed the laboratory did not have documentation of previously analyzed samples. 5. In interview on June 12, 2019, the Laboratory Director stated a comparison study was performed with Lab Corp for the validation study. At 1:24 pm, The Laboratory Director stated she did not have the data for the comparison studies included in the validation binder.
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: Based on record review and interview with personnel, the laboratory failed to provide documentation that the Clinical Consultant met education requirements for moderate complexity testing. Refer to D6057.
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by:

	Based on record review and interview with personnel, the laboratory failed to ensure the Clinical Consultant met education requirements. Findings: 1. Review of personnel records for the Clinical Consultant revealed the laboratory did not have documentation of her education. 2. In interview on June 14, 2019 at 1:24 pm, the Laboratory Director stated she was unable to get in touch with the Clinical Consultant to get a copy of her medical degree. The Laboratory Director confirmed the laboratory did not have documentation of education for the Clinical Consultant.