Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0464385	01/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Allen L Spires, Md, Amc	301 Davenport Avenue, Mer Rouge, 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	A Recertification Survey was performed at Allen Spires, M.D. - CLIA # 19D0464385 on January 8, 2018. Allen Spires, M.D. was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.801 CONDITION: Enrollment and testing of samples 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
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 observation, record review, and interview with laboratory personnel, the laboratory failed to enroll in a HHS approved proficiency testing program for Complete Blood Count (CBC) with automated differential testing. Findings: 1. Observation by surveyor during laboratory tour on January 8, 2018 revealed the laboratory utilizes a Horiba ABX Micros 60 Hematology analyzer for the testing and reporting of Complete Blood Count (CBC) with automated differentials. 2. Review of Proficiency Testing (PT) records for 2016 and 2017 revealed the laboratory had enrolled in Hematology Proficiency Testing (PT) with the American Academy of Family Physicians (AAFP). 3. Further review of proficiency testing records revealed

	the laboratory was not enrolled in PT for Hematology testing for 2018. 4. In interview on January 8, 2018, Personnel 6 verified that the laboratory was not enrolled in PT for Hematology testing for 2018. 5. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 11,568 CBCs with automated differential 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: Based on observation, 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 ensure written policies and procedures were established to assess competency for the laboratory's Technical Consultant. Refer to D5209 I. 2. The laboratory failed to establish and follow written policies and procedures to assess employee competency. Refer to D5209 II. 3. The laboratory failed to properly fill BD collection tubes to the quantity indicated as required by the maufacturer's instructions. Refer to D5311. 4. The laboratory failed to have a Quality Assurance Policy to identify any of the deficiencies identified with the preanalytic system. Refer to D5391. 5. The laboratory failed to ensure the policy and procedure manual contained a detailed policy and procedure for the mean and assay range verification of new lots of quality control. Refer to D5403. 6. The laboratory failed to perform calibration procedures on the Horiba ABX Micros 60 Hematology Analyzer utilized for Complete Blood Count (CBC) testing every 6 months. Refer to D5439. 7. The laboratory failed to verify the means for Quality Control (QC) material for Hematology testing prior to use. Refer to D5469. 8. The laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. 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: ***REPEAT DEfICIENCY from survey date May 24, 2016*** I. Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures were established to assess competency for the laboratory's Technical Consultant. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not establish written policies and procedures for personnel competency assessments of the Technical Consultant. 2. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed Personnel 2 listed as Technical Consultant. 3. Review of personnel records revealed a competency assessment was not performed for the duties of Technical Consultant by the Laboratory Director for Personnel 2. 4. In interview on January 8, 2018, Personnel 6

	confirmed there was no competency assessment performed for the Technical Consultant. II. Based on review of laboratory policy and procedure manual, and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess employee competency. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to establish written policies and procedures that include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel involved in any phase of 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. Interview with Personnel 6 on January 8, 2018 confirmed the laboratory failed to have a detailed written policy and procedure that included the six (6) mandated items.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to properly fill BD collection tubes to the quantity indicated as required by the maufacturer's instructions. Findings: 1. Observation by surveyor on January 8, 2018 revealed the laboratory utilized the lavender BD vacutainer collection tubes for CBC testing. 2. Review of the Horiba ABX Micros 60 Hematology Analyzer users manual revealed the following: "specimen collection and mixing: The sample collection tube must be filled to the exact quantity of blood indicated on the tube itself. Any incorrectly measured blood sample collections will show a variation in results." 3. Further observation by surveyors revealed short samples in the BD collection tubes for one (1) of five (5) patient samples: Patient 11 - less than 1/10th full 4. In Interview with Personnel 3 on January 8, 2018, she stated that she was unaware of the manufacturer's requirements and confirmed the observation stated above.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory's system failed to

	monitor, assess, and correct problems, identified with the preanalytic system. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory failed to have a Quality Assurance Policy to identify any of the deficiencies identified with the preanalytic system. 2. The laboratory failed to follow manufacturer requirements for specimen collection and mixing of tubes used for Complete Blood Count (CBC) testing. Refer to D5311. 4. In interview on January 8, 2018, Personnel 6 confirmed the laboratory's system failed to monitor, assess, and correct problems identified with the preanalytic system.
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 ensure the policy and procedure manual contained a detailed policy and procedure for the mean and assay range verification of new lots of quality control. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a policy and procedure to verify the mean and assay ranges of a new lot of quality control to include but not limited to: *How to establish ranges for quality control material and/or verification of quality control material; who is to monitor and how changes are to be made to the ranges of quality control material; and that the correct means and ranges are available to testing personnel. Also to include what quality control is required and the acceptablility criteria for each. 2. Further review of the laboratory's policy and procedure manual revealed the laboratory had a quality control policy but did not include the above information. 3. In interview on January 8, 2018, Personnel 6 confirmed the laboratory did not have a detailed policy and procedure manual for mean and assay range verification.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions;

	(b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: ***REPEAT DEFICIENCY from survey date May 24, 2016*** Based on observation, record review, and interview, the laboratory failed to perform calibration procedures on the Horiba ABX Micros 60 Hematology Analyzer utilized for Complete Blood Count (CBC) testing every 6 months. Findings: 1. Observation by surveyors during the tour of the laboratory on January 8, 2018 revealed the laboratory maintained a Horiba ABX Micros 60 Hematology Analyzer utilized for Complete Blood Count (CBC) testing. 2. Review of the laboratory's Policy and Procedure manual revealed the laboratory is to perform and document calibration procedures, at least every 6 months or as required due to manufacturer's recommendation, change in lot number of reagent, or other indicators that may affect patient testing. 3. Review of the calibration logs revealed the laboratory performed a calibration only once annually for 2016 and 2017 on the following dates: a) May 23, 2016 b) March 22, 2017 4. Review of the Task 1 & 3 provided by the laboratory revealed 11,568 Hematology tests are reported annually. 5. Interview with Personnel 6 on January 8, 2018 confirmed the laboratory did not perform calibration every six (6) months during the above period as required.
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 verify the means for Quality Control (QC) material for Hematology testing prior to use. Findings: 1. Observation by surveyor during laboratory tour on January 8, 2018 revealed the laboratory utilizes the Horiba ABX Micros 60 anakyzer with Horiba Minotrol 16 Tri-Level Controls for Complete Blood Count (CBC) testing. 2. Review of the Minotrol 16 Tri-Level Controls package insert under "Performance and characteristics" section revealed "Assay values on a new lot of control should be confirmed before it is put into routine use. The laboratory recovered mean should be within the assay range." 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written policy for the verification of QC means and ranges. 3. Review of the laboratory's QC records revealed the laboratory did not have documentation of verification of new lot QC means prior to use or runs concurrent with previous lot for the following lot numbers: Lot # MX409 Lot # MX408 Lot # MX407 Lot # MX406 Lot # MX405 6. In interview on January 8, 2018, Personnel 3 stated new lots of quality control were put into use without verification of means.
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 written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. Findings: 1. A review of patient test records and quality control records indicated problems found in the analytic systems as follows: a) The laboratory failed to ensure the policy and procedure manual contained a detailed policy and procedure for the mean and assay range verification of new lots of quality control. Refer to D5403. b) The laboratory failed to perform calibration procedures on the Horiba ABX Micros 60 Hematology Analyzer utilized for Complete Blood Count (CBC) testing every 6 months. Refer to D5439. c) The laboratory failed to verify the means for Quality Control (QC) material for Hematology testing prior to use. Refer to D5469. 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory did not establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems. 3. Interview with Personnel 6 on January 8, 2018 confirmed the laboratory did not identify and correct the issues cited above.
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 the laboratory personnel were performing test methods as required for accurate and reliable results. Refer to D6014. 2. The Laboratory Director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. Refer to D6015. 3. The Laboratory Director failed to ensure that the quality control program was maintained to assure quality laboratory services were provided. Refer to D6020. 4. 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. 5. The Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6030.
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: ***REPEAT DEFICIENCY from survey date May 24, 2016*** Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required for accurate and reliable results. Findings: 1. The laboratory failed to follow manufacturer requirements for specimen collection and mixing of tubes used for Complete Blood Count (CBC) testing Refer to D5311. 2. The laboratory failed to ensure the policy and procedure manual contained a detailed policy and procedure for the mean and assay range verification of new lots of quality control. Refer to D5403. 3. The laboratory failed to perform calibration procedures on the Horiba ABX Micros 60 Hematology Analyzer utilized for Complete Blood Count (CBC) testing every 6 months. Refer to D5439.
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 that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. Refer to D2000.
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 the quality control program was maintained to assure quality laboratory services were provided. 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: ***REPEAT DEFICIENCY from survey date May 24, 2016*** 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. The laboratory's system failed to monitor, assess, and correct problems, identified with the preanalytic system. Refer to D5391. 2. The laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. Refer to D5791.
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: ***REPEAT DEFICIENCY from survey date May 24, 2016*** Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. The laboratory failed to establish and follow written policies and procedures to assess employee competency. Refer to D5209 I. 2. The laboratory failed to ensure written policies and procedures were established to assess competency for the laboratory's Technical Consultant. Refer to D5209 II.
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 Consultants failed to provide technical and scientific oversight for the laboratory. Refer to D6036. 3. The Technical Consultant failed to ensure enrollment and participation in an HHS approved proficiency testing program. Refer to D6041. 4. The Technical Consultant failed to evaluate and document personnel competency annually in 2016 for three (3) of three (3) testing personnel reviewed. Refer to D6054.
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: ***REPEAT DEFICIENCY from survey date May 24, 2016*** 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 failed to have a copy of the Technical Consultant's current state license, 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 Personnel 6 on January 8, 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 Consultants failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to follow manufacturer requirements for specimen collection and mixing of tubes used for Complete Blood Count (CBC) testing. Refer to D5311. 2. The laboratory failed to ensure the policy and procedure manual contained a detailed policy and procedure for the mean and assay range verification of new lots of quality control. Refer to D5403. 3. The laboratory failed to perform calibration procedures on the Horiba ABX Micros 60 Hematology Analyzer utilized for Complete Blood Count (CBC) testing every 6 months. Refer to D5439. 4. The laboratory failed to verify the means for Quality Control (QC) material for Hematology testing prior to use. Refer to D5469.
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 enrollment and participation in an HHS approved proficiency testing program. Refer to D2000.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to evaluate and document personnel competency annually in 2016 for three (3) of three (3) testing personnel reviewed. Findings: 1. Review of personnel records on January 8, 2018 revealed the Technical Consultant failed to perform competency assessments in 2016 for the following personnel performing moderate complexity testing: Personnel 3 Personnel 4 Personnel 5 2. In interview on January 8, 2018, Personnel 6 confirmed annual competency assessment was not documented for all testing personnel in 2016.