Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1102844	05/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Immediate Care Of Oklahoma-Healthplex	3321 W Tecumseh Rd, Ste 125, Norman, OK	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The findings were discussed with the technical consultant and the office assistant at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 1. D5024: 493.1215: Condition: Hematology 2. D6000: 493.1403: Condition: Laboratory Director, Moderate Complexity 3. D6033: 493.1409: Condition: Technical Consultant, Moderate Complexity 4. D6063: 493.1421: Condition: Testing Personnel, Moderate Complexity
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 a review of the manufacturer's instructions, and interview with the technical consultant and office assistant, the laboratory failed to follow the manufacturer's instructions for waived testing. Findings include: (1) During the survey, the technical consultant stated to the surveyor the laboratory performed fecal occult blood testing using the Beckman Coulter Hemoccult test cards and developing solution; (2) The surveyor reviewed the manufacturer's instructions (package insert) for the test. Under "Precautions" it stated, "Because this test is visually read and requires color differentiation, it should not be interpreted by individuals with blue color deficiency (blindness)"; (3) The surveyor asked the technical consultant if the 9 individuals listed on the "Laboratory Personnel Report (Form 209)" completed by the laboratory prior to the survey, would perform the test, and interpret and report the results. The technical consultant stated to the surveyor all testing persons would perform, interpret, and report the results of the test if it was ordered on a patient; (4) The surveyor reviewed the personnel records for the testing persons but did not find documentation a color blindness test had been conducted for 9 of the 9 testing persons; (5) The

	surveyor asked the technical consultant and the office assistant if color blindness screening had been performed on the testing persons. The technical consultant and the office assistant stated to the surveyor color blindness screening had not been performed; (6) The surveyor reviewed the manufacturer's instructions with the technical consultant and the office assistant who stated to the surveyor, the laboratory did not follow the manufacturer's instructions for waived testing.
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 review of records, manufacturer's instructions, written policies and procedures, and interview with the technical consultant and office assistant, the laboratory failed to ensure the requirements were met for the specialty of Hematology. Findings include: (1) The laboratory failed to have a written policy and procedure for assessing employee competency. Refer to D5209: (2) The laboratory failed to review and evaluate results obtained on proficiency testing and perform corrective action for a proficiency testing failure. Refer to D5211; (3)The laboratory failed to ensure the manufacturer's environmental specifications were met. Refer to D5413; (4) The laboratory failed to analyze at least two levels of quality control materials each day of patient testing. Refer to D5447; (5) The laboratory failed to have an ongoing mechanism for performing quality assessment. Refer to D5791; (6) The laboratory failed to provide reference intervals appropriate for the patient population it serviced. Refer to D5807.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on interview with the technical consultant and the office assistant, the laboratory failed to have a written policy and procedure for assessing employee competency. Findings include: (1) At the beginning of the survey, the surveyor asked the technical consultant and the office assistant if the laboratory had a written policy and procedure which explained how employees were assessed for testing competency; (2) The technical consultant and office assistant stated to the surveyor a written competency policy had not been written. NOTE: For non-waived testing, the regulations require initial training, a semiannual evaluation during the first year, and an annual evaluation thereafter for each testing person for ensuring competency. The policy/procedure for evaluating competency must include, but is not limited to: *Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing *Monitoring the recording and reporting of test results *Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance

	records *Direct observation of performance of instrument maintenance and function checks *Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples *Assessment of problem solving skills
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records, and interview with the technical consultant, the laboratory failed to review and evaluate results obtained on proficiency testing and for a proficiency testing failure. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory used the Medonic M-series analyzer to perform patient CBC (Complete Blood Count) testing, which included WBC (White Blood Count); (2) Hematology proficiency testing records for 2017 and 2018 to date were reviewed. The surveyor could not locate documentation which proved corrective action had been taken for an unacceptable proficiency testing result in the Third 2017 event for WBC: (a) The laboratory failed the result for 1 of the 5 samples and attained a score of 80%; (b) For sample HD-12, the laboratory reported "19.0." The proficiency testing program's acceptable response was, "1.6-2.3." (3) The surveyor reviewed the findings with the technical consultant and asked if corrective action (e.g., review of analyzer printouts, submitted results, etc.) had been taken to determine the cause of the failure. The technical consultant reviewed the records and stated to the surveyor corrective action had not been taken for the failure.
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 a review of records, manufacturer's instructions, and interview with the technical consultant and the office assistant, the laboratory failed to ensure the manufacturer's environmental requirements were met. Findings include: LABORATORY TEMPERATURE (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory performed patient CBC (Complete Blood Count) testing (i.e. WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, MCHC- Mean Corpuscular Hemoglobin Concentration, Platelet Count, automated WBC differentials (percent and absolute totals) of Lymphocytes, Mid/Monos, and Granulocytes, etc.) using the Medonic M-series hematology analyzer; (2) The surveyor reviewed the manufacturer's operator manual for the analyzer. The manufacturer required an operating temperature between 18 and

	32 degrees C (Centigrade); (3) The surveyor then reviewed temperature logs for 7 months (January, June, September, and December 2017; January, February, and April 2018) and identified the laboratory failed to monitor the temperature to ensure the manufacturer's operating requirements for the analyzer had been met on 7 of the 123 days reviewed: (a) January 2017: Day 27 (b) June 2017: Days 3,24 (c) December 2017: Days 1,2,26 (d) January 2018: Day 31 (4) The surveyor reviewed the findings with the technical consultant who stated to the surveyor the laboratory failed to monitor and document the temperature of the laboratory as listed above. LABORATORY HUMIDITY (1) The surveyor reviewed the operator's manual for the analyzer and identified the manufacturer required an operating humidity between 10 and 90% for the analyzer; (2) The surveyor then reviewed humidity logs for 7 months (January, June, September, and December 2017; January, February, and April 2018) and identified the laboratory failed to monitor the humidity to ensure the manufacturer's operating requirements for the analyzer had been met on 7 of the 123 days reviewed: (a) January 2017: Day 27 (b) June 2017: Days 3,24 (c) December 2017: Days 1,2,26 (d) January 2018: Day 31 (3) The surveyor reviewed the findings with the technical consultant who stated to the surveyor the laboratory failed to monitor and document the humidity of the laboratory as listed above.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and the office assistant, the laboratory failed to analyze two levels of quality control materials each day of patient testing. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory performed patient CBC (Complete Blood Count) testing (i.e. WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, MCHC- Mean Corpuscular Hemoglobin Concentration, Platelet Count, automated WBC differentials (percent and absolute totals) of Lymphocytes, Mid/Monos, and Granulocytes, etc.) using the Medonic M-series hematology analyzer. In addition, the technical consultant stated to the surveyor the laboratory analyzed 3 levels (Low, Normal, and High) of QC (Quality Control) (Boule Con-Diff) materials each day of patient testing; (2) The surveyor reviewed QC records for the testing performed during 7 months (January, February, June, September, and December 2017; and January and April 2018). The surveyor identified patient testing was performed and there was no documentation which proved QC materials had been analyzed: (a) 02/18/17: (i) Patient #1-CBC testing performed at 11:38 AM (ii) Patient #2-CBC testing performed at 06:31 PM (b) 06/02 /17: (i) Patient #3-CBC testing performed at 02:55 PM (ii) Patient #4-CBC testing performed at 04:09 PM (3) The surveyor reviewed the records with the technical consultant and the office assistant who stated the laboratory failed to analyze two levels of QC materials each day patient testing was performed.
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 a review of records, manufacturer's instructions, and interview with the technical consultant and the office assistant, the laboratory failed to have an effective ongoing mechanism for performing analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment due to the following issues identified during the survey: (a) The laboratory failed to ensure the manufacturer's environmental requirements were met. Refer to D5413; (b) The laboratory failed to analyze two levels of quality control each day of patient testing. Refer to D5447.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of records, and interview with the technical consultant, the laboratory failed to ensure normal reference intervals appropriate for the patient population serviced by the laboratory, were made available to the provider reponsible for using the test results. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory performed CBC (Complete Blood Count) (i.e., RBC-Red Blood Count, Hgb-Hemoglobin, Hct-Hematocrit, etc.) testing using the Medonic M-series hematology analyzer; (2) The surveyor reviewed four patient CBC reports as follows: (a) Patient #5: Adult male. Testing performed on 08/18/17 (b) Patient #6: Adult male. Testing performed on 01/18/18 (c) Patient #7: Adult female. Testing performed 01/20/18 (d) Patient #8: Adult female. Testing performed on 01/20/18 (3) The four test reports included the same reference intervals for the following CBC analytes: (a) RBC: 3.50 - 5.50 (b) Hgb: 11.5 - 16.5 (c) Hct: 35.0 - 55.0 (4) The surveyor reviewed the findings with the technical consultant and asked if the laboratory had gender specific normal CBC reference intervals. The technical consultant stated to the surveyor, the laboratory did not have gender specific reference intervals for the CBC analytes listed above, which were made available to the provider using the test results. NOTE: Routinely, female reference intervals for analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.
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 a review of records, manufacturer's instructions, and interview with the technical consultant and the office assistant, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to ensure proficiency testing results were reviewed and evaluated. Refer to D6018; (2) The laboratory director failed to ensure a quality control program had been established and maintained. Refer to D6020; (3) The laboratory director failed to ensure an effective mechanism for performing quality assessment had been established and maintained. Refer to D6021; (4) The laboratory director failed to ensure normal reference intervals appropriate for the patient population serviced by the laboratory were available to the provider. Refer to D6026; (5) The laboratory director failed to ensure laboratory personnel performing moderate complexity testing had the appropriate education and training. Refer to 6028; (6) The laboratory director failed to ensure the laboratory had a written policy and procedure for performing testing person competency. Refer to D6030.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of records, and interview with the technical consultant, the laboratory director failed to ensure the laboratory reviewed and evaluated proficiency testing results to identify problems that require corrective action. Findings include: (1) The laboratory director failed to review and evaluate proficiency testing results. Refer to D5211.
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 a review of records, manufacturer's instructions, and interview with the technical consultant and the office assistant, the laboratory director failed to ensure an effective quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure the

	manufacturer's environmental specifications for the hematology analyzer were met. Refer to D5413; (2) The laboratory director failed to ensure two levels of quality control were analyzed each day of patient testing. Refer to D5447.
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 a review of records, manufacturer's instructions, and interview with the technical consultant and the office assistant, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure there was an effective mechanism for performing quality assessment due to the issues identified during the survey. 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 a review of records and interview with the technical consultant, the laboratory director failed to ensure test reports included pertinent information required for interpretation. Findings include: (1) The laboratory director failed to ensure normal reference intervals appropriate for the patient population serviced by the laboratory, were made available to the provider reponsible for using the test results. Refer to D5807.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

	This STANDARD is not met as evidenced by: Based on a review of records, and interview with the technical consultant, the laboratory director failed to ensure laboratory personnel who performed moderate complexity testing had the appropriate training and education to accurately perform and report testing results in accordance with the personnel responsibilities as described in this subpart. Findings include: TRAINING (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, Platelet Count, etc.) using the Medonic M-series analyzer; (2) During the survey, the surveyor identified 4 previously employed individuals not listed on the Form CMS-209 who had performed the moderate complexity testing: testing persons #5, #6, #7, and #8. The surveyor then reviewed the personnel records but could not find documentation which proved the previously employed testing persons had been initially trained to perform the moderate complexity testing; (3) The surveyor asked the technical consultant for training documentation for testing persons #5, #6, #7, and #8 to review. The technical consultant stated to the surveyor after the testing persons terminated their employment, the personnel records were sent to another site for storage and there were no training documents available for review. Therefore, the surveyor could not verify the previously employed testing persons #5, #6, #7, and #8 had been initially trained to perform the moderate complexity testing. EDUCATIONAL QUALIFICATIONS (1) The laboratory director failed to ensure individuals who performed moderate complexity testing met the educational qualifications as listed in 493.1423. Refer to D6065.
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 interview with the technical consultant and the office assistant, the laboratory director failed to ensure a written policy and procedure was established for monitoring individuals who conduct preanalytical, analytical, and postanalytic phases of testing to assure 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. The findings include: (1) The laboratory director failed to ensure a written policy and procedure for assessing employee competency had been written. Refer to D5209.
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 a review of records, manufacturer's instructions, written policies and procedures, and interview with the technical consultant and the office assistant, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure individuals who performed the duties of the technical consultant met the educational qualifications and experience. Refer to D6035; (2) The technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042; (3) The technical consultant failed to ensure the testing competency of testing persons performing moderate complexity testing had been assessed and evaluated at least annually. 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: Based on a review of records, and interview with the technical consultant and the office assistant, the technical consultant failed to ensure individuals who performed the duties of a technical consultant met the educational qualifications and experience as defined in 493.1411. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, Platelet Count, etc.) using the Medonic M-series analyzer which is moderate complexity testing; (2) The surveyor reviewed the Laboratory Personnel Report (Form CMS-209) completed by the laboratory prior to the survey. The form indicated the technical consultant also performed the moderate complexity testing; (3) The surveyor then reviewed personnel records and identified the following: (a) Office assistant: (i) Performed the competency assessment for the technical consultant on 06/15/17; (ii) Obtained a high school diploma. (b) Previous administrator: (i) Performed the competency assessment for testing person #3 on 05/24 /17; (ii) There was no educational documentation (i.e., diploma, transcript) located in the personnel records; (iii) The surveyor could not determine if the individual qualified as a technical consultant. (4) The surveyor asked the technical consultant if educational documents were available for the previous administrator. The technical consultant explained all personnel records for individuals no longer working in the facility had been taken to another site for storage and were not available; (5) The surveyor explained records for employees were to be maintained at the facility for at least 2 years after the individual no longer performed patient testing. The surveyor also reviewed the findings with the technical consultant who stated to the surveyor, the laboratory failed to ensure individual who performed competency assessments, met the educational requirements of a technical consultant.
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 a review of records, manufacturer's instructions, and interview with the technical consultant and the office assistant, the technical consultant failed to establish a quality control program appropriate for the testing performed and establish the parameters for acceptable levels of analytic performance and ensure that these levels were maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. Findings include: (1) The technical consultant failed to ensure the laboratory had a written policy and procedure for assessing employee competency. Refer to D5209; (2) The technical consultant failed to ensure the laboratory met the manufacturer's environmental requirements for the hematology analyzer. Refer to D5413; (3) The technical consultant failed to ensure two levels of quality control materials were analyzed each

	day of patient testing. Refer to D5447; (4) The technical consultant failed to ensure reference intervals appropriate for the patient population serviced by the laboratory were made available to the provider for interpretation. Refer to D5807.
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 a review of records and interview with the technical consultant, the technical consultant failed to evaluate testing persons performing moderate complexity testing at least annually. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, Platelet Count, etc.) using the Medonic M-series analyzer; (2) During the survey, the surveyor identified 4 previously employed testing persons who had performed the moderate complexity testing, not listed on the Form CMS-209: testing persons #5, #6, #7, and #8; (3) The surveyor then reviewed the personnel records but could not find records for the 4 previously employed testing persons. The surveyor asked the technical consultant for the 2017 competency assessments performed for testing persons #5, #6, #7, and #8. The technical consultant explained after the testing persons terminated their employment, all records were sent to another site for storage and were not available for review; (4) The surveyor explained to the technical consultant that laboratory records were required to be maintained for at least 2 years and easily retrievable within a timely manner, and because the records were not available, the surveyor could not verify the technical consultant had performed annual competency assessments in 2017 for testing persons #5, #6, #7, and #8.
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 a review of records and interview with the technical consultant, the laboratory failed to ensure individuals who performed moderate complexity testing met the educational qualification requirements as listed in 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of testing performed. Findings include: (1) Testing persons did not meet the educational qualification requirements for performing moderate complexity testing. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the

	laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure testing persons met the required educational qualifications to perform moderate complexity testing. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, Platelet Count, etc.) using the Medonic M-series analyzer; (2) During the survey, the surveyor identified 4 previously employed individuals who had performed the moderate complexity testing, not listed on the Form CMS-209: testing persons #5, #6, #7, and #8. The surveyor then reviewed the personnel records but could not find the educational documents (i.e. transcript, diploma, GED certificate) for the 4 previously employed testing persons; (3) The surveyor asked the technical consultant if educational documentation for testing persons #5, #6, #7, and #8 were available for review. The technical consultant stated to the surveyor after the testing persons terminated their employment, the personnel records were sent to another site for storage and there were no educational documents available for review. Therefore, the surveyor could not verify the previously employed testing persons #5, #6, #7, and #8 met the educational qualifications for performing moderate complexity testing.