Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0469542	06/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Kelley Family Clinic	13190 Ne 23rd St, Choctaw, 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 recertification survey was performed on 06/19/19. The laboratory was found out of compliance with the following CLIA regulations: 493.1215: D5024: Condition: Hematology 493.1403: D6000: Condition: Laboratory Director, Moderate Complexity 493.1409: D6033: Condition: Technical Consultant 493.1421: D6063: Condition: Testing Personnel, Moderate Complexity
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of records and interview with \testing person #1 and the laboratory director, the laboratory failed to ensure proficiency testing samples were tested by personnel who routinely performed patient testing. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor the moderate complexity laboratory testing performed was CBC (Complete Blood Count) (i.e. WBC (White Blood Count), RBC (Red Blood Count), Hemoglobin, Hematocrit, Platelet Count, etc.) testing; (2) The surveyor reviewed the Laboratory Personnel Report (Form CMS-209) completed prior to the survey. The form listed 4 testing persons (testing person #1, testing person #2, testing person #3, and the laboratory director) as performing the moderate complexity testing in the laboratory. The surveyor then reviewed personnel records and identified one individual (testing person #4) had not been listed on the Laboratory Personnel Report (Form CMS-209); (3) The surveyor then reviewed Hematology proficiency testing records for 5 proficiency testing events (Third 2017 Event; First, Second, and Third 2018 Events; and the First 2019 Event). The surveyor identified there was no documentation which proved testing person #2, testing person #3, and testing person #4 analyzed proficiency

	testing in 5 of the 5 proficiency testing events; (4) The surveyor asked the laboratory director and testing person #1 if testing person #2, testing person #3, and testing person #4 had been trained and performed CBC testing. The laboratory director and testing person #1 stated to the surveyor, testing person #2, testing person #3, and testing person #4 had been trained and performed patient CBC testing; (5) The surveyor reviewed the findings with the laboratory director and testing person #1, who stated to the surveyor the laboratory failed to ensure proficiency testing had been performed by all testing persons who routinely performed patient testing.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1 and the laboratory director, the testing person failed to sign the statement attesting proficiency testing samples were analyzed in the same manner as patient specimens. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor the moderate complexity laboratory testing performed was CBC (Complete Blood Count) (i.e. WBC (White Blood Count), RBC (Red Blood Count), Hemoglobin, Hematocrit, Platelet Count, etc.) testing; (2) The surveyor then reviewed Hematology proficiency testing records for 5 proficiency testing events (Third 2017 Event; First, Second, and Third 2018 Events; and the First 2019 Event). From the review, the surveyor identified in 1 of the 5 events (Second 2018 Event), the attestation statement had not been signed by the testing person who analyzed the proficiency testing samples; (3) The surveyor reviewed the findings with testing person #1 and the laboratory director, who stated to the surveyor, the testing person who analyzed the proficiency testing, had not signed the attestation statement.
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, observation, and interview with testing person #1 and the laboratory director, the laboratory failed to ensure the requirements were met for the specialty of Hematology. Findings include: (1) The laboratory failed to ensure the manufacturers' environmental specifications and

	storage requirements were met. Refer to D5413; (2) The laboratory failed to demonstrate the performance specifications for a new test method. Refer to D5421; (3) The laboratory failed to have control procedures that monitored the accuracy and precision of the testing process. Refer to D5441; (4) The laboratory failed to have an ongoing mechanism for performing quality assessment. Refer to D5791. NOTE: D5024 was cited at the previous recertification survey performed 08/23/17.
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, observation, and interview with testing person #1, the laboratory failed to ensure the manufacturers' environmental specifications and storage requirements were met. Findings include: HUMIDITY (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory replaced the Beckman Coulter AcT diff 2 hematology analyzer with the Sysmex XP-300 hematology analyzer on 05/29/18 to perform CBC (WBC-White Blood Count), RBC (Red Blood Count), Hemoglobin, Hematocrit, Platelet Count, etc.) testing; (2) The surveyor reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required a humidity between 30 and 85%; (3) The surveyor then reviewed the laboratory's humidity records from 06/01/18 through 06/19/19 (the humidity was documented twice daily-morning and afternoon). The acceptable humidity range on the laboratory's log was, "Less than 85%" which allowed humidity less than the manufacturer's required minimum of 30%. From the review, the surveyor identified the humidity was unacceptable during 7 of the 13 months reviewed. The specific findings follow: (a) June 2018: 1 of 32 humidity readings was unacceptable: (i) Morning: (aa) Day 12: The humidity was 28% (b) July 2018: 4 of 42 humidity readings were unacceptable: (i) Morning: (aa) Day 23: The humidity was 20% (bb) Days 5,20: The humidity was 28% (ii) Afternoon: (aa) Day 20: The humidity was 25% (c) November 2018: 1 of 40 humidity readings was unacceptable: (i) Afternoon: (aa) Day 12: The humidity was 29% (d) December 2018: 3 of 16 humidity readings were unacceptable: (i) Morning: (aa) Day 4: The humidity was 27% (bb) Day 3: The humidity was 28% (cc) Day 10: The humidity was 29% (e) January 2019: 19 of 44 humidity readings were unacceptable: (i) Morning: (aa) Days 29,30,31: The humidity was 23% (bb) Days 2,4,21: The humidity was 25% (cc) Days 3,11,28: The humidity was 27% (dd) Day 25: The humidity was 29% (ii) Afternoon: (aa) Day 30: The humidity was 23% (bb) Day 31: The humidity was 25% (cc) Days 2,4,21: The humidity was 27% (dd) Day 29: The humidity was 28% (ee) Days 11,24,25: The humidity was 29% (f) February 2019: 17 of 38 humidity readings were unacceptable: (i) Morning: (aa) Days 20,21: The humidity was 21% (bb) Days 1,8,18,19: The humidity was 23% (cc) Day 25: The humidity was 25% (dd) Day 26: The humidity was 28% (ee) Day 15: The humidity was 29% (ii) Afternoon: (aa) Day 8: The humidity was 21% (bb) Day 1: The humidity was 23% (cc) Days 19,20: The humidity was 25% (dd) Days 18,21,25: The humidity

was 27% (ee) Day 26: The humidity was 28% (g) March 2019: 8 of 42 humidity readings were unacceptable: (i) Morning: (aa) Days 15,18: The humidity was 28% (bb) Days 1,4,7: The humidity was 29% (ii) Afternoon: (aa) Days 1,22: The humidity was 27% (bb) Day 7: The humidity was 29% (4) The surveyor reviewed the findings with testing person #1 and the laboratory director who stated to the surveyor, the laboratory failed to ensure the manufacturer's humidity requirement had been met, as listed above. REFRIGERATOR TEMPERATURE (1) Testing person #1 stated to the surveyor, the laboratory analyzed three levels of QC (Quality Control) materials each day of patient testing. In addition, testing person #1 stated the following: (a) Beckman Coulter 4C-ES Cell Control (Abnormal Low, Normal, and Abnormal High) QC materials had been used with the Beckman Coulter AcT diff 2 analyzer until it was replaced on 05/28/18. The manufacturer required the QC materials be stored at 35-46 degrees F(Fahrenheit) (2-8 degrees C [Centigrade]); (b) Sysmex EIGHTCHECK-3WP X-TRA (Low, Normal, and High) QC materials were used with the Sysmex XP-300 analyzer from 05/29/18 through the day of the survey. The manufacturer required the QC materials be stored at 35-46 degrees F (2-8 degrees C). (2) The surveyor observed the laboratory and identified a small Black & Decker refrigerator located in the laboratory. Testing person #1 stated to the surveyor opened vials of QC materials that were being used daily, were stored in the refrigerator; (3) The surveyor then reviewed temperature records for the refrigerator from 09/01/17 through the day of the survey (the temperature was documented twice daily-morning and afternoon). The laboratory's acceptable storage temperature range was 35-46 degrees F. The surveyor identified during 14 of the 21 months reviewed, the refrigerator temperatures were colder than the manufacturer's acceptable limits. The specific findings follow: (a) February 2018: 9 of the 30 refrigerator readings were too cold: (i) Morning: (aa) Day 14: The temperature was 32 degrees F (bb) Days 12,13,15: The temperature was 34 degrees F (ii) Afternoon: (aa) Days 14,15,26: The temperature was 32 degrees F (bb) Days 12,13: The temperature was 34 degrees F (b) March 2018: 11 of the 42 refrigerator readings were too cold: (i) Morning: (aa) Day 9: The temperature was 30 degrees F (bb) Day 7: The temperature was 32 degrees F (cc) Days 8,14,25: The temperature was 34 degrees F (ii) Afternoon: (aa) Days 5,7,8: The temperature was 32 degrees F (bb) Days: 6,9,14: The temperature was 34 degrees F (c) April 2018: 1 of 35 refrigerator readings was too cold: (i) Morning: (aa) Day 11: The temperature was 34 degrees F (d) June 2018: 1 of 32 refrigerator readings was too cold: (i) Morning: (aa) Day 4: The temperature was 34 degrees F (e) July 2018: 36 of 42 refrigerator readings was too cold: (i) Morning: (aa) Days 13,18,20,24,25,26: The temperature was 30 degrees F (bb) Days 2,10,11,12,16,17,27,30,31: The temperature was 32 degrees F (cc) Days 9,19,23: The temperature was 34 degrees F (ii) Afternoon: (aa) Days 10,12,13,20,24,26,30: The temperature was 30 degrees F (bb) Days 2,9,11,16,17,19,23,25,27,31: The temperature was 32 degrees F (cc) Day 18: The temperature was 34 degrees F (f) August 2018: 26 of 42 refrigerator readings were too cold: (i) Morning: (aa) Days 1,6: The temperature was 30 degrees F (bb) Days 8,9,10,13,14,15,16,17,20,21: The temperature was 32 degrees F (cc) Days 2,3: The temperature was 34 degrees F (ii) Afternoon: (aa) Days 2,8,16: The temperature was 30 degrees F (bb) Days 1,6,9,10,13,14,17,20,21: The temperature was 32 degrees F (g) October 2018: 14 of 42 temperature readings were too cold: (i) Morning: (aa) Days 5,8,9,10,11,23,26,29,30,31: The temperature was 34 degrees F (ii) Afternoon: (aa) Day 12: The temperature was 32 degrees F (bb) Days 5,10,23: The temperature was 34 degrees F (h) November 2018: 15 of 40 temperature readings were too cold: (i) Morning: (aa) Day 1,2,5,6,7: The temperature was 32 degrees F (bb) Days 8,9,12: The temperature was 34 degrees F (ii) Afternoon: (aa) Days 2,7,8: The temperature was 32 degrees F (bb) Days 1,5,6,9: The temperature was 34 degrees F (i) December 2018: 5 of 16 temperature readings were too cold: (i) Morning: (aa) Days 3,4: The

	temperature was 32 degrees F (bb) Day 7: The temperature was 34 degrees F (ii) Afternoon: (aa) Day 3: The temperature was 32 degrees F (bb) Day 11: The temperature was 34 degrees F (j) January 2019: 44 of 44 temperature readings were too cold: (i) Morning: (aa) Days 16,17,21,22,24,25: The temperature was 28 degrees F (bb) Days 18,23,31: The temperature was 30 degrees F (cc) Days 2,3,4,7,8,9,10,11,14,15,28,29,30: The temperature was 32 degrees F (ii) Afternoon: (aa) Days 18,23,24: The temperature was 28 degrees F (bb) Days 15,16,17,21,22,25: The temperature was 30 degrees F (cc) Days 2,3,8,9,10,14,28,29,30,31: The temperature was 32 degrees F (dd) Days 4,7,11: The temperature was 34 degrees F (k) February 2019: 37 of 38 temperature readings were too cold: (i) Morning: (aa) Day 11: The temperature was 28 degrees F (bb) Days 6,14,15,26: The temperature was 30 degrees F (cc) Days 1,4,5,7,8,13,18,19,20,21,25,27,28: The temperature was 32 degrees F (dd) Day 12: The temperature was 34 degrees F (ii) Afternoon: (aa) Days 1,20: The temperature was 30 degrees F (bb) Days 4,5,6,7,8,13,14,15,18,19,21, 25,26,27,28: The temperature was 32 degrees F (cc) Day 12: The temperature was 34 degrees F (l) March 2019: 42 of 42 temperature readings were too cold: (i) Morning: (aa) Day 18: The temperature was 28 degrees F (bb) Days 6,8: The temperature was 30 degrees F (cc) Days 1,4,5,7,11,14,15,19,21,22,25, 26,27,28,29: The temperature was 32 degrees F (dd) Days 12,13,20: The temperature was 34 degrees F (ii) Afternoon: (aa) Day 7: The temperature was 30 degrees F (bb) Days 1,4,5,6,8,12,14,15,18,19,22, 25,26,27,28,29: The temperature was 32 degrees F (cc) Days 11,13,20,21: The temperature was 34 degrees F (m) April 2019: 41 of 42 temperature readings were too cold and 1 of 42 temperatures had not been documented: (i) Morning: (aa) Days 1,5: The temperature was 30 degrees F (bb) Days 2,3,4,8,9,10,11,12,15,16,17,18,19, 22,23,24,29,30:The temperature was 32 degrees F (cc) Day 25: The temperature was 34 degrees F (ii) Afternoon: (aa) Days 4,11,12: The temperature was 30 degrees F (bb) Days 1,2,3,5,8,9,10,15,16,17,18,19,23, 24,29,30: The temperature was 32 degrees F (cc) Day 22: The temperature was 34 degrees F (dd) Day 25: The temperature had not been documented (n) June 2019: 22 of 24 temperature readings were too cold: (aa) Morning: (i) Days 3,4,10,11,12,14,18: The temperature was 32 degrees F (ii) Days 7,13,17: The temperature was 34 degrees F (bb) Afternoon: (i) Days 3,4,5,6,10,11: The temperature was 32 degrees F (ii) Days 7,12,13,14,17,18: The temperature was 34 degrees F (4) The surveyor reviewed the findings with testing person #1 and the laboratory director who stated to the surveyor the laboratory failed to ensure the manufacturers' temperature requirement had been met, as listed above. NOTE: D5413 was cited at the previous recertification survey performed 08/23/17.
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 a review of records and interview with testing person #1 and the laboratory director, the laboratory failed to verify reference intervals were appropriate for use

	with a new test method. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory replaced the Beckman Coulter AcT diff 2 hematology analyzer with the Sysmex XP-300 hematology analyzer on 05/29 /18 to perform CBC (WBC-White Blood Count), RBC (Red Blood Count), Hemoglobin, Hematocrit, Platelet Count, etc.) testing; (2) The surveyor reviewed the validation records for the new analyzer but could not find documentation whether the reference intervals (normal ranges) used with the Sysmex XP-300 had been established or verified. The surveyor asked testing person #1 how the laboratory determined the reference ranges for the testing performed on the new analyzer. Testing person #1 stated to the surveyor, the laboratory used the same normal CBC reference intervals which had been used with the previous hematology analyzer; (3) The surveyor asked testing person #1 if the laboratory verified the reference intervals from the previous analyzer were appropriate for use with the new Sysmex XP-300 analyzer before being put into use. Testing person #1 stated to the surveyor the laboratory did not verify the reference intervals used on the previously used analyzer were acceptable for patient testing performed with the new Sysmex XP-300 analyzer; (4) For examples of patient CBC testing performed when the laboratory failed to verify the reference intervals used with the new Sysmex XP-300 analyzer, refer to D5441.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1 and the laboratory director, the laboratory failed to have control procedures that monitored the accuracy and precision of the testing process. Findings include: (1) At the beginning of the survey, testing person #1 stated the following to the surveyor: (a) The laboratory began using the Sysmex XP-300 hematology analyzer on 05/29/18 to perform CBC (WBC-White Blood Count), RBC (Red Blood Count), Hemoglobin, Hematocrit, Platelet Count, etc.); (b) Three levels (Low, Normal, and High) of EIGHTCHECK-3WP X-TRA QC (Quality Control) materials were tested each day of patient testing. (2) The surveyor reviewed QC records and identified 18 QC lot numbers were used from 05/29/18 through the day of the survey. For 18 of the 18 lot numbers, there were no records (i.e., Levey-Jennings data, statistical reports, etc.) proving the control results had been monitored for variances (i.e. shifts and trends); (3) The surveyor asked testing person #1 and the laboratory director if QC results had been monitored for variances. The laboratory director stated to the surveyor they could not print the Levey-Jennings graphs from the Sysmex XP-300 analyzer and the QC data had not been monitored for variances; (4) The following were examples of patient CBC testing performed when the laboratory had not monitored QC results for variances: (a)

	Patient #1 - Testing performed 06/04/18 (b) Patient #2 - Testing performed on 06/13 /18 (c) Patient #3 - Testing performed on 06/27/18 (d) Patient #4 - Testing performed on 07/09/18 (e) Patient #5 - Testing performed on 07/27/18 (f) Patient #6 - Testing performed on 08/13/18 (g) Patient #7 - Testing performed on 08/23/18 (h) Patient #8 - Testing performed on 09/12/18 (i) Patient #9 - Testing performed on 09/26/18 (j) Patient #10 - Testing performed on 10/03/18 (k) Patient #11 - Testing performed on 10 /31/18 (l) Patient #12 - Testing performed on 11/05/18 (m) Patient #13 - Testing performed on 11/29/18 (n) Patient #14 - Testing performed on 12/07/18 (o) Patient #15 - Testing performed on 12/26/18 (p) Patient #16 - Testing performed on 01/03/19 (q) Patient #17 - Testing performed on 01/29/19 (r) Patient #18 - Testing performed on 02/05/19 (s) Patient #19 - Testing performed on 02/18/19 (t) Patient #20 - Testing performed on 02/26/19 (u) Patient #21 - Testing performed on 03/13/19 (v) Patient #22 - Testing performed on 03/25/19 (w) Patient #23 - Testing performed on 04/09/19 (x) Patient #24 - Testing performed on 04/29/19 (y) Patient #25 - Testing performed on 05/03/19 (z) Patient #26 - Testing performed on 05/20/19 (aa) Patient #27 - Testing performed on 06/03/19 (bb) Patient #28 - Testing performed on 06/10/19
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, manufacturers' instructions, observation, and interview with testing person#1 and the laboratory director, the laboratory to have an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic system. Findings include: (1) The laboratory failed to ensure the manufacturers' environmental specifications and storage requirements were met. Refer to D5413; (2) The laboratory failed to verify reference intervals were appropriate for use with a new test method. Refer to D5421; (3) The laboratory failed to have control procedures that monitored the accuracy and precision of the testing process. Refer to D5441. NOTE: D5791 was cited at the previous recertification survey performed 08 /23/17.
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, manufacturers' instructions, observation, and interview with testing person #1 and the laboratory director, the laboratory director failed to provide overall management and direction as listed at 493.1407 of this subpart. Findings include:(1) The laboratory director failed to ensure patient reference ranges had been verified for a new test system. Refer to D6013; (2) The laboratory director failed to ensure proficiency testing samples were tested as required under Subpart H.

	Refer to D6016; (3) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Refer to D6020; (4) The laboratory director failed to ensure an effective quality assessment program had been established and maintained. Refer to D6021; (5) The laboratory director failed to ensure laboratory personnel performing moderate complexity testing met the required qualifications. Refer to D6028. NOTE: D6000 was cited at the previous recertification survey performed 08/23/17.
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 a review of records, and interview with testing person #1 and the laboratory director, the laboratory director failed to ensure verification procedures for a new test system were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure patient reference ranges had been verified for a new test system. Refer to D5421.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1 and the laboratory director, the laboratory director failed to ensure proficiency testing samples were tested as required under Subpart H. Findings include: (1) The laboratory director failed to ensure that proficiency testing samples were tested by personnel who routinely performed patient testing. Refer to D2007; (2) The laboratory director failed to ensure attestation statements were signed by the testing person attesting proficiency testing samples were analyzed in the same manner as patient specimens. Refer to D2015.
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, observation, and interview with testing person #1 and the laboratory director, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory failed to ensure the manufacturers' environmental specifications and storage requirements were met. Refer to D5413; (2) The laboratory director failed to ensure control procedures monitored the accuracy and precision of the testing process. Refer to D5441. NOTE: D6020 was cited at the previous recertification survey performed 08 /23/17.
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, observation, and interview with testing person #1 and the laboratory director, the laboratory director failed to ensure an effective quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791. NOTE: D6021 was cited at the previous recertification survey performed 08 /23/17.
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 office manager, the laboratory director failed to ensure laboratory personnel who performed moderate complexity

	testing had the appropriate education to accurately perform and report testing results in accordance with the personnel responsibilities as described in this subpart. Findings include: (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.
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, and interview with testing person #1 and the laboratory manager, 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 performance specifications had been demonstrated for a new test system. Refer to D6040; (2) The technical consultant failed to ensure the establishment and maintenance of a quality control program that ensure acceptable levels of analytic performance. Refer to D6042. NOTE: D6033 was cited at the previous recertification survey performed 08/23/17.
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 a review of records and interview with testing person #1 and the laboratory director, the technical consultant failed to ensure that verification procedures were adequate to determine the performance characteristics. Findings include: (1) The technical consultant failed to ensure the reference ranges were verified for a new test system. Refer to D5421.
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, observation, and interview with testing person #1, the office manager, and the laboratory director, the technical consultant failed to ensure the establishment and maintenance of acceptable levels of

	analytic performance. Findings include: (1) The technical consultant failed to ensure the manufacturers' environmental specifications and storage requirements were met. Refer to D5413; (2) The technical consultant failed to ensure the laboratory had control procedures that monitored the accuracy and precision of the testing process. Refer to D5441; (3) The technical consultant failed to ensure individuals who performed moderate complexity testing met the educational qualifications as listed in 493.1423. Refer to D6065. NOTE: D6042 was cited at the previous recertification survey performed 08/23/17.
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 office manager, the technical consultant failed to ensure a testing person met the required educational qualifications to perform moderate complexity testing as listed at 493.1423. Findings include: (1) The technical consultant failed to ensure individuals who performed moderate complexity testing met the minimum educational requirements. 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 office manager, the laboratory failed to ensure a testing person met the required educational qualifications to perform moderate complexity testing. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor the moderate complexity testing performed by the laboratory was CBC (Complete Blood Count) testing performed on the Sysmex XP-330 hematology analyzer; (2) The surveyor reviewed the Laboratory Personnel Report (CMS Form-209) completed by the laboratory prior to the survey. The form listed 4 testing persons who performed the moderate complexity laboratory testing (Testing person #1, testing person #2, testing person #3, and the laboratory director); (3) The surveyor then reviewed personnel records for the testing persons and identified one individual who had performed testing from May 2018 through February 2019 (testing person #4). The surveyor could not find education documents (a

	minimum of a high school diploma/transcript or equivalent - GED) for the individual; (5) The surveyor asked the office manager if educational documents were available for testing person #4. The office manager stated to the surveyor there were no educational documents available for testing person #4. Therefore, the surveyor could not verify testing person #4 met the educational requirements for moderate complexity testing.