Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2088219	06/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Labcorp Oklahoma, Inc Cityplex	2408 E 81st St, Ste 105, Tulsa, 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 survey was performed 06/26/18 through 06/28/18. The laboratory was found out of compliance with the following CLIA regulations: 493.1215: D5024: Condition: Hematology 493.1250: D5400: Condition: Analytic Systems 493.1407: D6000: Condition: Laboratory Director, Moderate Complexity The findings were reviewed with the technical consultant and the patient services director at the conclusion of the survey.
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, and interview with the technical consultant, the patient services director, testing person #1, and testing person #2, the laboratory failed to ensure the requirements were met for the specialty of Hematology. Findings include: (1) The laboratory failed to follow the manufacturer's instructions for testing performed. Refer to D5411; (2) The laboratory failed to demonstrate the performance specifications for a new test system. Refer to D5421; (3) The laboratory failed to follow the manufacturer's specifications for control materials. Refer to D5479.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that

	provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, policies and procedures, and interview with the technical consultant, the patient services director, testing person #1, and testing person #2, the laboratory failed to monitor and evaluate the overall quality of analytic systems. Findings include: (1) The laboratory failed to ensure the laboratory's policies and procedures were followed. Refer to D5401; (2) The laboratory failed to follow the manufacturer's instructions for the testing performed. Refer to D5411; (3) The laboratory failed to demonstrate the performance specifications for a new test method. Refer to D5421; (4) The laboratory failed to perform the manufacturers' required maintenance procedures. Refer to D5429; (5) The laboratory failed to have quality control procedures that monitored the accuracy and precision of the analytic process. Refer to D5441; (6) The laboratory failed to document the reactivity of the H&E stain quality control slide each day of patient testing. Refer to D5473; (7) The laboratory failed to follow the manufacturer's specifications for control materials. Refer to D5479; (8) The laboratory failed to ensure permanent testing records were maintained. Refer to D5787; (9) The laboratory failed to have an effective ongoing mechanism for performing analytic quality assessment. Refer to D5791. NOTE: D5400 was cited on the initial certification survey performed 06/14/16-06/16/16.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the technical consultant and the patient services director, the laboratory failed to follow its policy and procedure for storage of blood components. Findings include: (1) On the second day of the survey, the surveyor reviewed the "Testing Component Storage Equipment Alarms" policy and procedure for the blood bank refrigerator, which stated the following: (a) High alarm activation: (i) After the low alarm activation check is performed, "Remove the sensor and adjust the temperature of the water back to about 4 degrees C;" (ii) "Allow the thermometer to equilibrate to the temperature of the water;" (iii) "Place the sensor into the cup or beaker. With continuous stirring, slowly add room temperature water to create a slow rise in temperature of about 0.5 degrees C per minute" (iv) "The alarm should sound at 5.5 degrees C;" (v) "Evaluate acceptability of results." (2) The surveyor then reviewed the quarterly refrigerator alarm check records from 01/01/17 through 06/27/18. The records indicated 3 of the 4 quarterly refrigerator high alarm checks performed during the review period were unacceptable, as follows: (a) 02/28/17: The high temperature check activated the alarm at 6.0 degrees C (b) 08/28/17: The high temperature check activated the alarm at 6.0 degrees C (c) 11/30/17: The high temperature check activated the alarm at 6.0 degrees C (3) The surveyor reviewed the findings with the technical consultant and

	the patient services director, who stated to the surveyor the laboratory failed to follow its policy for the acceptable limits of the high alarm checks, as listed above. NOTE: D5401 was cited on the initial certification survey performed 06/14/16-06/16/16.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the patient services director, and testing person #1, the laboratory failed to follow the manufacturer's instructions for the testing performed. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor the laboratory discontinued using the Stago Satellite coagulation analyzer and replaced it with the ACL TOP 300 analyzer on 11/10/17 to perform PT/INR (Protime/International Normalized Ratio), PTT (Partial Thromboplastin Time), D-dimer, Fibrinogen, and Anti-Xa testing on 11/10/17; (2) The surveyor reviewed the laboratory's implementation records and identified the laboratory's reference intervals (i.e. normal patient ranges) were established using 45 patients, instead of the 120 patients as required by the manufacturer for a full reference interval study when a new instrument and/or methodology is put into use for patient testing; (3) The surveyor asked the technical consultant and the patient services director if the laboratory had conducted a full reference interval study using 120 patients for the testing performed on the new analyzer. The technical consultant and the patient services director stated to the surveyor, the laboratory did not perform a full reference study for the testing performed on the new analyzer; (4) The surveyor then asked the technical consultant and the patient services director for the manufacturer's implementation instructions. The technical consultant and the patient services director explained there were no instructions available. (During the survey, testing person #1 contacted the manufacturer for instructions, but the documentation had not been received by the laboratory prior to the conclusion of the survey); (5) After the survey (06/29/18), the surveyor reviewed the surveyor's copy of the manufacturer's instructions. It included the following instructions: (a) "Establishing a Normal Reference Interval:" (i) "Reference intervals should be established whenever there is a change in instrumentation and/or methodology, lot number of reagent, sample collection procedures, and at least once a year;" (ii) "Be performed for all tests performed on the analyzer;" (iii) "The number of samples can vary depending on whether the laboratory is establishing a new platform/methodology, or new analyte." (b) "Specimen Collection and Preparation:" (i) "The number of samples used can vary depending on whether the laboratory is establishing a full reference interval (120 normal donors) or attempting to verify a range established elsewhere (different laboratory, literature source, etc.) (20 normal donors)." (6) The surveyor then contacted the technical consultant and the patient services director via email and explained the laboratory failed to follow the manufacturer's instructions which stated a full 120 reference interval study must be performed on a new testing platform/methodology for all the analytes tested with the ACL Top 300 analyzer. The technical consultant and the patient services director agreed the laboratory failed to follow the manufacturer's instructions for establishing reference intervals for the testing performed on the ACL

	Top 300 analyzer; (7) Examples of patient testing performed when the laboratory failed to follow the manufacturer's requirements for establishing reference intervals follow: (a) PT/INR and PTT: (i) Patient #31: Testing performed on 11/14/17 (ii) Patient #34: Testing performed on 12/05/17 (iii) Patient #35: Testing performed on 12 /07/17 (iv) Patient #36: Testing performed on 01/03/18 (v) Patient #37: Testing performed on 01/31/18 (vi) Patient #38: Testing performed on 02/05/18 (vii) Patient #39: Testing performed on 02/06/18 (viii) Patient #40: Testing performed on 03/02/18 (ix) Patient #41: Testing performed on 03/09/18 (x) Patient #42: Testing performed on 04/03/18 (xi) Patient #43: Testing performed on 04/05/18 (xii) Patient #44: Testing performed on 05/02/18 (xiii) Patient #45: Testing performed on 05/04/18 (xiv) Patient #46: Testing performed 05/17/18 (xv) Patient #47: Testing performed on 06/04/18 (xvi) Patient #48: Testing performed 06/18/18 (b) PT/INR:Patient #33: Testing performed on 11/21/17 (c) PTT:Patient #32: Testing performed on 11/14/17 (d) D-dimer: (i) Patient #49: Testing performed on 11/30/17 (ii) Patient #34: Testing performed on 12/05/17 (iii) Patient #50: Testing performed on 12/14/17 (iv) Patient #51: Testing performed on 01/08/18 (v) Patient #39: Testing performed on 02/06/18 (vi) Patient #52: Testing performed on 03/02/18 (vii) Patient #53: Testing performed on 03/08/18 (viii) Patient #54: Testing performed on 04/04/18 (ix) Patient #55: Testing performed on 04/12/18 (x) Patient #46: Testing performed 05/17/18 (e) Fibrinogen: (i) Patient #56: Testing performed on 11/29/17 (ii) Patient #34: Testing performed on 12/05/17 (iii) Patient #46: Testing performed on 05/17/18 (f) Anti-Xa: (i) Patient #57: Testing performed on 01/15/18 (ii) Patient #58: Testing performed on 01/16/18 NOTE: D5411 was cited on the initial certification survey performed 06/14 /16-06/16/16.
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 the technical consultant, the patient services director, and testing person #2, the laboratory failed to demonstrate the performance specifications for a new test system. Findings include: (1) On the first day of the survey, the technical consultant and the patient services director stated to the surveyor the laboratory used the Hemachron Signature Elite analyzer (serial #13390) and ACT-LR cuvettes into use to perform ACT (Activated Clotting Time) testing on 06/12/17; (2) On the third day of the survey, the surveyor reviewed the validation records for the Hemochron Signature Elite analyzer but could not locate documentation which showed the performance specifications (i.e. accuracy, precision, and reportable range) had been demonstrated on the Hemachron Signature Elite analyzer; (3) The surveyor then reviewed test records and identified the analyzer had been used to perform patient testing beginning on 06/12/17 through the third day of the survey; (4) The surveyor asked the technical consultant and the patient services director for documentation to prove the performance specifications had been demonstrated on the analyzer before it was used for patient testing; (5) The technical

	consultant, the patient services director, and testing person #2 could not locate the validation records prior to the conclusion of the survey. The technical consultant and patient services director stated to the surveyor documentation that showed laboratory demonstrated the performance specifications for the analyzer, could not be located; (6) Examples of patient ACT testing performed when the laboratory failed to demonstrate the accuracy, precision, and reportable range for the Hemachron Signature Elite analyzer prior to performing patient testing, include the following: (a) Patient #1: Testing performed on 06/13/17 (b) Patient #2: Testing performed on 06/19 /17 (c) Patient #3: Testing performed on 06/29/17 (d) Patient #4: Testing performed on 07/05/17 (e) Patient #5: Testing performed on 07/19/17 (f) Patient #6: Testing performed on 07/31/17 (g) Patient #7: Testing performed on 08/01/17 (h) Patient #8: Testing performed on 08/08/17 (i) Patient #9: Testing performed on 08/30/17 (j) Patient #10: Testing performed on 09/12/17 (k) Patient #11: Testing performed on 09 /22/17 (l) Patient #12: Testing performed on 10/04/17 (m) Patient #13: Testing performed on 10/27/17 (n) Patient #14: Testing performed on 11/02/17 (o) Patient #15: Testing performed on 11/27/17 (p) Patient #16: Testing performed on 12/15/17 (q) Patient #17: Testing performed on 12/28/17 (r) Patient #18: Testing performed on 01/02/18 (s) Patient #19: Testing performed on 01/16/18 (t) Patient #20: Testing performed on 01/30/18 (u) Patient #21: Testing performed on 02/07/18 (v) Patient #22: Testing performed on 02/28/18 (w)Patient #23: Testing performed on 03/07/18 (x) Patient #24: Testing performed on 03/19/18 (y) Patient #25: Testing performed on 03/29/18 (z) Patient #26: Testing performed on 04/18/18 (aa) Patient #27: Testing performed on 04/30/18 (bb) Patient #28: Testing performed on 05/07/18 (cc) Patient #29: Testing performed on 05/30/18 (dd) Patient #30: Testing performed on 05/16/18 NOTE: D5421 was cited on the initial certification survey performed 06/14/16-06/16 /16.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant and the patient services director, the laboratory failed to perform the manufacturers' required maintenance procedures. Findings include: BECKMAN COULTER AU480 CHEMISTRY ANALYZER (1) On the first day of the survey, the technical consultant and the patient services director stated to the surveyor the laboratory performed Chemistry testing (i.e., Albumin, Amylase, Glucose, Potassium, Sodium, Direct Bilirubin, etc.) using the Beckman Coulter AU480 chemistry analyzer, put into use in January 2017; (2) On the second day of the survey, the surveyor reviewed records from 01/01/17 through the second day of the survey. The surveyor identified the manufacturer's required monthly maintenance procedures, as recorded on the AU480 Maintenance Schedule log, were as follows: (a) Clean sample and reagent probe wash wells (b) Clean the mix bar wash wells (c) Clean the wash nozzle unit and check the tube mounting joints (d) Clean the deionized water tank (e) Clean the deionized water and sample probe filters (3) From the review, the surveyor identified the required monthly maintenance procedures had not been documented as performed in 1 of the 18 months reviewed: September 2017; (4) The surveyor reviewed the findings with the technical consultant and the laboratory services

	director who stated to the surveyor there was no documentation which showed the laboratory performed the manufacturer's required monthly maintenance procedures, as listed above. AP LEICA CM 1850UV CRYOSTAT (1) On the first day of the survey, the technical consultant and the patient services director stated to the surveyor the laboratory performed microscopic interpretations of slides made from surgical tissue specimens. The tissue specimens were frozen and sectioned using the AP Leica CM 1800UV cryostat. The tissue was placed on slides, fixed, stained with H&E (Hematoxylin and Eosin), dried, coverslipped, and examined microscopically for diagnosis; (2) On the third day of the survey, the surveyor reviewed the manufacturer's instructions for performing the daily maintenance procedure on the cryostat, which were, "Clean the instrument every day;" (3) The surveyor then reviewed the cryostat maintenance log from 01/01/17 through 06/28/18 and identified the daily maintenance had not been documented as performed on 4 of the 31 days of patient testing reviewed during the review period: (a) 01/27/17 (b) 09/29/17 (c) 10/14 /17 (d) 12/05/17 (4) The surveyor reviewed the maintenance records with the technical consultant and the patient services director, who stated to the surveyor the daily maintenance had not been documented as performed on the 4 days of patient testing, as listed above. NOTE: D5429 was cited on the initial certification survey performed 06/14/16-06/16/16.
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 the technical consultant and the patient services director, the laboratory failed to have quality control procedures that monitored over time the accuracy and precision of the analytic process for Chemistry testing. Findings include: (1) On the first day of the survey, the technical consultant and the patient services director stated to the surveyor the laboratory put the Beckman Coulter AU480 analyzer into use in January 2017 to perform chemistry testing (e.g., Albumin, Amylase, Glucose, Potassium, Sodium, Direct Bilirubin, etc.) and the laboratory analyzed two levels (Level 1 and Level 3) of Bio-Rad Liquid Assayed Multiqual control materials each day of patient testing to monitor the accuracy of the testing; (2) On the third day of the survey, the surveyor requested QC (quality control) records from 5 months (May and September 2017; and February, March, and May 2018). For 3 of the 5 months reviewed (September 2017, and February and March 2018), the records did not include Levey-Jennings graphs, peer review, etc. The surveyor asked the technical consultant and the patient services director for the Levey-Jennings graphs or peer review data for the months listed above. The technical consultant explained that the graphs had not been printed each month and the laboratory did not have peer data, but the QC results had been reviewed each day for

	acceptability; (3) The surveyor asked the technical consultant and the patient services director if the laboratory had another method that would monitor over time the accuracy and precision of test performance that might be influenced by changes in the test system performance and environmental conditions, and variances in operator performance. The technical consultant and the patient services director stated to the surveyor the laboratory did not use another method to monitor over time the accuracy and precision of test performance. NOTE: D5441 was cited on the initial certification survey performed 06/14/16-06/16/16.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (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 patient services director, the laboratory failed to document the reactivity of the H&E stain quality control slide each day of patient testing. Findings include: (1) On the first day, of the survey, the technical consultant and the patient services director stated to the surveyor the laboratory performed microscopic interpretations of slides made from surgical tissue specimens. The tissue specimens were frozen and sectioned using the AP Leica CM 1800UV cryostat. The tissue was placed on slides, fixed, stained with H&E (Hematoxylin and Eosin), dried, coverslipped, and examined microscopically for diagnosis; (2) On the third day of the survey, the surveyor asked the technical consultant and the patient services director to explain the laboratory's QC (quality control) procedure for the staining. The technical consultant and the patient services director explained the acceptability of the staining was noted on the patient testing log by the pathologist examining the patient slides; (3) The surveyor reviewed the patient testing logs from 01/01/17 through 06/28/18 and identified on 1 day of the 31 days of patient testing reviewed, a question mark was noted for the reactivity of the H&E stain QC, instead of whether the stain was acceptable or unacceptable (Patient #59-Testing performed on 10/09/17); (4) The surveyor reviewed the findings with the technical consultant and the patient services director who stated to the surveyor, the laboratory failed to document the reactivity of the QC slide for the 1 day of patient testing listed above.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. 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 patient services director, the laboratory failed to follow

	the manufacturer's specifications for control materials. Findings include: (1) On the first day of the survey, the technical consultant and the patient services director stated to the surveyor, the laboratory performed ACT (Activated Clotting Time) testing using the Hemochron Signature Elite analyzer and ACT-LR cuvettes. In addition, 2 levels (Normal and Abnormal) of directCHECK Whole Blood control materials were tested each 8 hours of patient testing; (2) On the third days of the survey, the surveyor reviewed the manufacturer's specifications (package insert) for the quality control materials. It stated the following, "Accriva recommends that each institution establish its own expected range of response based on the +/- standard deviations of at least 20 repeated test results. The local mean values established should fall within the manufacturer's acceptable performance range. Studies show that intra-laboratory variation in test results should produce a coefficient of variation of approximately 14% or less for coagulation control tests."; (3) The surveyor then reviewed QC (Quality Control) records from 06/12/17 through the third day of the survey. For 12 of the 12 months reviewed, there was no evidence the laboratory established their own expected range of response as required in the manufacturer's specifications; (4) The surveyor reviewed the findings with the technical consultant and the patient services director. The technical consultant and the patient services director stated to the surveyor, the laboratory failed to follow the manufacturer's specifications for establishing its own expected range of response for the QC materials; (5) Lot numbers of QC materials used when the laboratory failed to follow the manufacturer's specifications, follow: (a) Normal Control: 3 of 3 lot numbers: (i) Lot #C7DNL011: (aa) Used from 06/12/17-09/29/17 and (bb) Used from 02/06/18-02/09/18 (ii) Lot #F7DNL018: Used from 09/29/17- 02/06/18 (iii) Lot #J7DN027: Used from 02/12/18 through the third day of the survey (b) Abnormal Control: 3 of 3 lot numbers (i) Lot #C7DLA012: Used from 06/12/17- 08/11/17 (ii) Lot #C7DLA015: Used from 08/11 /17- 10/27/17 (iii) Lot #G7DLA025: Used from 10/27/17 through the third day of the survey (6) The following are examples of patient ACT testing performed when the laboratory failed to follow the manufacturer's specifications for the quality control materials: (a) Patient #1: Testing performed on 06/12/17 (b) Patient #2: Testing performed on 06/13/17 (c) Patient #3: Testing performed on 06/14/17 (d) Patient #4: Testing performed on 06/19/17 (e) Patient #5: Testing performed on 06/29/17 (f) Patient #6: Testing performed on 07/05/17 (g) Patient #7: Testing performed 07/07/17 (h) Patient #8: Testing performed on 07/19/17 (i) Patient #9: Testing performed on 07 /31/17 (j) Patient #10: Testing performed on 08/01/17 (k) Patient #11: Testing performed on 08/08/17 (l) Patient #12: Testing performed on 08/30/17 (m) Patient #13: Testing performed on 09/12/17 (n) Patient #14: Testing performed on 09/22/17 (o) Patient #15: Testing performed on 10/04/17 (p) Patient #16: Testing performed on 10/27/17 (q) Patient #17: Testing performed on 11/02/17 (r) Patient #18: Testing performed on 11/27/17 (s) Patient #19: Testing performed on 12/15/17 (t) Patient #20: Testing performed on 12/28/17 (u) Patient #21: Testing performed on 01/02/18 (v) Patient #22: Testing performed on 01/02/18 (w) Patient #23: Testing performed on 01 /16/18 (x) Patient #24: Testing performed on 01/30/18 (y) Patient #25: Testing performed on 02/07/18 (z) Patient #26: Testing performed on 02/28/18 (aa) Patient #27: Testing performed on 03/07/18 (bb) Patient #28: Testing performed on 03/19/18 (cc) Patient #29: Testing performed on 03/29/18 (dd) Patient #30: Testing performed on 04/18/18 (ee) Patient #31: Testing performed on 04/30/18 (ff) Patient #32: Testing performed on 05/07/18 (gg) Patient #33: Testing performed on 05/16/18 (hh) Patient #34: Testing performed on 05/30/18 NOTE: D5479 was cited on the initial certification survey performed 06/16/16-06/18/16.
D5787	TEST RECORDS CFR(s): 493.1283(a)

	The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and the patient services director, the laboratory failed to ensure permanent testing records were maintained. Findings include: (1) On the first day of the survey, the technical consultant and the patient services director stated to the surveyor the laboratory performed microscopic interpretations of slides made from surgical tissue specimens. The tissue specimens were frozen and sectioned using the AP Leica CM 1800UV cryostat. The tissue was placed on slides, fixed, stained with H&E (Hematoxylin and Eosin), dried, coverslipped, and examined microscopically for diagnosis; (2) On the third day of the survey, the surveyor reviewed records for the testing from 01/01/17 through 06/28/18. The surveyor identified from the review, records which had been documented in pencil: (a) Cryostat temperatures: (i) October 2017: Days 17,18 (ii) November 2017: Days, 2,3,4,5,6,7,8,14, 15,16,17,23 (iii) January 2018: Days 8,9,10,11,12,15,23 (iv) April 2018: Days 2,4,5,6,9,10 (v) May 2018: Days 15,25 (b) Patient testing records: (i) Patient #60: Testing performed on 10/04/17 (ii) Patient #61: Testing performed on 10/09/17 (iii) Patient #62: Testing performed on 10/12/17 (iv) Patient #63: Testing performed on 10/24/17 (v) Patient #64: Testing performed on 10 /24/17 (vi) Patient #65: Testing performed on 11/30/17 (vii) Patient #66: Testing performed on 01/11/18 (viii) Patient #67: Testing performed on 01/18/18 (ix) Patient #68: Testing performed on 02/03/18 (x) Patient #69: Testing performed on 02/08/18 (xi) Patient #70: Testing performed on 02/13/18 (xii) Patient #71: Testing performed on 06/19/18 (xiii) Patient #72: Testing performed on 06/28/18 (xiv) Patient #73: Testing performed on 06/28/18 (3) The surveyor reviewed the findings with the technical consultant and the patient services director and explained use of pencil does not ensure permanence of documentation. The technical consultant and the patient services director stated to the surveyor, the laboratory failed to maintain permanent laboratory records when documentation was recorded in pencil. NOTE: The Interpretive Guidelines at 493.1283(a) states, "Laboratory records should not be documented in pencil and the use of whiteout is not acceptable for making corrections."
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, the patient services director, testing person #1, and testing person #2, the laboratory failed to have an ongoing mechanism for performing effective

	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 follow its policy and procedure for storage of blood components. Refer to D5401; (b) The laboratory failed to follow the manufacturer's instructions for the testing performed. Refer to D5411; (c) The laboratory failed to demonstrate the performance specifications for a new test system. D5421; (d) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (e) The laboratory failed to have control procedures that monitored the accuracy and precision of the analytic process. Refer to D5441; (f) The laboratory failed to follow the manufacturer's specifications for control materials. Refer to D5479. NOTE: D5791 was cited on the initial certification survey performed 06/16/16-06/18/16.
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, policies and procedures, and interview with the technical consultant, the patient services director, and testing person #1, the laboratory director failed to provide overall management and direction for moderate complexity testing. Finding include: (1) The laboratory director failed to ensure verification procedures were adequate to determine the accuracy, precision, and other pertinent performance characteristics of a new test method. Refer to D6013; (2) 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 D6014; (3) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (4) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021. NOTE: D6000 was cited on the initial certification survey performed 06/14/16-06/16/16.
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, interview with the technical consultant, the patient services director, and testing person #1, the laboratory director failed to ensure that verification procedures used were adequate to determine performance characterisitics. Findings follow: (1) The laboratory director failed to ensure verification procedures

	were adequate to determine the accuracy, precision, and other pertinent performance characteristics of a new test method. Refer to D5421. NOTE: D6013 was cited on the initial certification survey performed 06/14/16-06/16/16.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, and the patient services 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 director failed to ensure the manufacturer's instructions were followed for the testing performed. Refer to D5411; (2) The laboratory director failed to ensure the manufacturer's maintenance procedures were performed as required. Refer to D5429; (3) The laboratory director failed to ensure the manufacturer's specifications were followed for control materials. Refer to D5479. NOTE: D6014 was cited on the initial certification survey performed 06/14/16-06/16/16.
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 patient services director, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure control procedures monitored over time the accuracy and precision of the analytic process for Chemistry testing. Refer to D5441. NOTE: D6020 was cited on the initial certification survey performed 06/14/16-06/16/16.
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, the patient services director, testing person #1, and testing person #2, 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, ongoing mechanism for performing effective analytic quality assessment. Refer to D5791. NOTE: D6021 was cited on the initial certification survey performed 06/14/16-06/16/16.
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 the technical consultant, patient services director, and testing person #2, the technical consultant failed to ensure verification procedures were adequate to determine the performance characteristics. Findings include: (1) The technical consultant failed to ensure the laboratory demonstrated the performance specifications for a new test method. 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, and interview with the technical consultant, and the patient services 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 control procedures monitored the accuracy and precision of the testing process over time. Refer to D5441.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

	This STANDARD is not met as evidenced by: Based on a review of patient test reports and interview with the technical consultant and the patient services director, testing personnel failed to follow the laboratory's procedure for test analysis. Findings include: (1) On the first day of the survey, the technical consultant and the patient services director stated to the surveyor the laboratory performed manual WBC (White Blood Cell) differentials on patient CBC's (Complete Blood Counts) which met specific criteria (i.e., flagged values, WBC counts below 2.0, etc.); (2) The technical consultant and the patient services director stated to the surveyor the laboratory performed a manual WBC differential microscopically on a stained peripheral blood smear. A total of 100 WBC's were counted and differentiated as Segmented Neutrophils (Segs), Bands, Lymphocytes (Lymphs), Monocytes (Monos), Eosinophils (Eos), Basophils (Basos), and Atypical Lymphocytes (Atyp Lymphs. The manual WBC differential results were reported along with the automated total WBC count obtained by the analyzer; (3) On the third day of the survey, the surveyor reviewed 58 patient reports, which contained flags chosen at random from 2 months (May 2017 and May 2018). The surveyor identified on 1 of the 58 reports, the moderate complexity manual WBC differential did not equal 100 cells, as follows: (a) Patient #74: Testing performed on 05/07/18-Total number of WBC's reported for the manual differential: 99 (i) Segs: 19 (ii) Lymphs: 79 (iii) Monos: 1 (4) The surveyor reviewed the findings with the technical consultant and the patient services director who verified the manual WBC differential listed above should have totaled 100 WBC's. The technical consultant and the patient services director stated to the surveyor, the laboratory failed to ensure testing personnel followed the laboratory's policy and procedure to report a total of 100 WBC's for the manual differential and failed to ensure testing personnel reported tests results accurately and reliably.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on a review of records, and interview with the technical consultant and the patient services director, the laboratory failed to ensure testing personnel followed the policy for performing test analyses. Findings include: (1) On the first day of the survey, the technical consultant and the patient services director stated to the surveyor the laboratory performed manual WBC (White Blood Cell) differentials on patient CBC's (Complete Blood Counts) which met specific criteria (i.e., flagged values, WBC counts below 2.0, etc.); (2) The technical consultant and the patient services director explained the manual WBC differentials were performed microscopically on a stained peripheral blood smear. It was the laboratory's policy to count a total of 100 WBC's and differentiate the WBC's as Segmented Neutrophils (Segs), Bands, Lymphocytes (Lymphs), Monocytes (Monos), Eosinophils (Eos), Basophils (Basos), Atypical Lymphocytes (Atyp Lymphs), and immature WBC forms, if present (i.e., Blasts, Metamyelocyte, etc.). The manual WBC differential was reported along with the automated total WBC count obtained by the analyzer; (3) On the third day of the survey, the surveyor reviewed 58 patient reports which obtained flags chosen at

	random from 2 months (May 2017 and May 2018). The surveyor identified 1 high complexity manual WBC differential performed, did not equal 100 WBC's, as follows: (a) Patient #75: Testing performed on 05/03/18-Total number of WBC's reported for the manual differential: 101 (i) Segs: 77 (ii) Bands: 1 (iii) Lymphs: 18 (iv) Monos: 2 (v) Eos: 1 (vi) Metamyelocyte: 1 (vii) Myelocyte: 1 (4) The surveyor reviewed the findings with the technical consultant and the patient services director who verified the high complexity manual WBC differential listed above should have totaled 100 WBC's. The technical consultant and the patient services director stated to the surveyor, the laboratory failed to ensure testing personnel followed the laboratory's policy and procedure to report a total of 100 WBC's for the manual differential and failed to ensure testing personnel reported tests results accurately and reliably.