Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475204	08/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hillcrest Hospital/Henryetta	2401 W Main St, Henryetta, 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 08/27/19-08/30/19. The laboratory was found out of compliance with the following CLIA regulations: 493.1215: D5024: Condition: Hematology 493.1217: D5026: Condition: Immunohematology 493.1403: D6000: Condition: Laboratory Director, Moderate Complexity 493.1409: D6033: Condition: Technical Consultant, Moderate Complexity 493.1441: D6076: Condition: Laboratory Director, High Complexity The findings were reviewed with the laboratory supervisor and testing person #1.
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 and interview with the laboratory supervisor and testing person #1, the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299 for the specialty of Hematology. Findings include: (1) The laboratory failed to follow the manufacturer's instructions for establishing pediatric normal reference intervals for coagulation and hematology. Refer to D5411; (2) The laboratory failed to perform maintenance procedures as required by the manufacturer. Refer to D5429.
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299.

	This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor and testing person #1, the laboratory failed to meet the requirements of 493.1230 through 493.1256, 493.1271, and 493.1281 through 493.1299 for the specialty of Immunohematology. Findings include: (1) The laboratory failed to ensure expired Blood Bank testing materials were not used. Refer to D5417.
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 laboratory supervisor, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, the surveyor reviewed the 2018 and 2019 proficiency testing records and identified in the Second Chemistry Core Event of 2019, the following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program): (a) Creatinine: 4 of 5 results exhibitied a Positive bias (i) CH-06: SDI 3.2 (ii) CH-07: SDI 2.3 (iii) CH-08: SDI 2.2 (iv) CH-10: SDI 2.0 (2) There was no documentation found in the records the laboratory identified and evaluated the biases to determine if a systematic failure had occurred which required the laboratory to take corrective action (e.g., review quality control, maintenance records, calibration, review of patient results, etc.) for the biases; (3) The surveyor reviewed the findings with the laboratory supervisor who stated to the surveyor the laboratory had not identified or evaluated the biases and had not taken corrective action.
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 laboratory supervisor and testing person #1, the laboratory failed to follow the manufacturer's instructions for establishing pediatric normal reference intervals for coagulation and hematology. Findings include: COAGULATION (1) On the first day of the survey, the laboratory supervisor stated to the surveyor the Sysmex CA-620 analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing. In addition, the current reagents in use were as follows: (a) PT Innovin, Lot #549730-Put into use on 07/09/19 (b) PTT Actin FSL, Lot #556970-Put into use on 07/09/19 (2) The surveyor reviewed the manufacturer's instructions for establishing normal reference intervals (the manufacturer required the establishment of a reference interval with a new analyzer

and verification of the normal reference interval with each reagent lot number rollover). The following was identified: (a) The manufacturer referred to CLSI C28-A3c document to establish a reference interval, which stated, "As indicated in this document, the working group endorses its previous recommendation that the best means to establish a reference interval is to collect samples from a sufficient number of qualified reference individuals to yield a minimum of 120 samples for analysis, by nonparametric means, for each partition (eg, sex, age range);" (b) "Reference Interval-A Reference Interval must be established for PT and PTT by each institution:" (i) "Donors must be from a healthy population (no known pathological conditions)" (ii) "Donors should not take any medications, including aspirin" (iii) "Donors should span the adult age range. (NOTE: A separate range should be established for pediatric populations)" (the note was written in bold lettering). (iv) "Calculate mean and 2 SD range" (v) "MNPT for INR calculation should be the geometric mean" (3) The surveyor asked the laboratory supervisor if pediatric coagulation testing was performed. The laboratory supervisor stated to the surveyor, the laboratory did not perform many coagulation tests on pediatric patients, but if ordered, the tests would be performed and the adult normal reference ranges would be used; (4) To determine if the laboratory should perform a 20 or a 120 normal sample study, the surveyor asked the laboratory supervisor and teting person #1 if the laboratory had established a normal reference interval for pediatric PT/INR and PTT testing prior to performing the testing on pediatric patients. The laboratory supervisor and testing person #1 stated there was no documentation a pediatric normal reference interval had been established with 120 normal samples prior to testing; (5) The surveyor then reviewed the PT Innovin and PTT Actin FSL new reagent number lot rollover records for 2018 and 2019 and identified the following: (a) 01/12/18: (i) PT Innovin reagent, Lot #549701 was put into use; (ii) The laboratory utilized 20 normal adult donor samples to verify a normal reference interval with the new reagent; (iii) A geometric mean of 10.2 was determined from the adult donor samples and used to calculate pediatric INR results. (b) 07/09/19: (i) PT Innovin reagent, Lot #549730 was put into use: (aa) The laboratory utilized 42 normal adult donor samples to verify a normal reference interval with the new reagent; (bb) A geometric mean of 10.2 was determined from the adult donor samples and used to calculate pediatric INR results. (ii) PTT Actin FSL reagent, Lot #556970 was put into use: (aa) The laboratory utilized 42 normal adult donor samples to verify a normal reference interval with the new reagent; (bb) The reference range determined from the adult donor samples was 23.7-28.9, and was used to evaluate pediatric patient results. (6) The surveyor reviewed the findings with the laboratory supervisor and testing person #1 during a phone conversation on 10/07 /19, who stated the following: (a) The laboratory did not perform a 120 sample study to establish a pediatric normal reference interval prior to beginning pediatric coagulation testing; (b) The reference ranges used for pediatric patients PT/INR and PTT testing were determined from adult donor samples, not pediatric donor samples at the reagent lot numbers rollover. (7) The following were examples of pediatric patients with coagulation testing performed when the normal reference intervals had not been established by performing a 120 normal sample study specifically for pediatric patients, as required: (a) Patient #67: Age 15 - PT/INR and PTT testing was performed on 06/04/18 (b) Patient #68: Age 7 - PT/INR and PTT testing was performed on 07/06/18 (c) Patient #69: Age 16 - PT/INR and PTT testing was performed on 07/06/18 (d) Patient #70: Age 17 - PT/INR testing was performed on 07 /16/18 (e) Patient #71: Age 17 - PT/INR and PTT testing was performed on 08/04/18 (f) Patient #72: Age 7 - PT/INR testing was performed on 03/27/19 HEMATOLOGY (1) On the first day of the survey, the laboratory supervisor stated to the surveyor the laboratory used the Sysmex XS-1000i analyzer to perform the following testing: (a) CBC (Complete Blood Count) testing (i.e., WBC-White Blood Count, RBC-Red

Blood Count, Hemoglobin, Hematocrit, Platelet, MCH-Mean Corpuscular Hemoglobin, MCHC-Mean Corpuscular Hemoglobin Concentration, MCV-Mean Corpuscular Volume, Platelet count, WBC differential (i.e. Neutrophils, Lymphocytes, Monocytes, Basophils, Eosinophils in percentage and number, etc.); (b) H&H (Hemoglobin and Hematocrit) (2) The surveyor asked the laboratory supervisor if the laboratory performed pediatric CBC testing. The laboratory supervisor stated the laboratory did not perform many pediatric CBC tests but if a test was ordered, it would be performed; (3) The surveyor reviewed the manufacturer's instructions for Reference Ranges. It stated the following: (a) Sample Selection: (i) "Establish criteria for 'healthy' individuals to select samples. For example:" (aa) "Normal donors may be defined as ones who have no clinical evidence of a medical disorder known to affect the CBC and differential." (bb) "Had no recent episode of bleeding or infection." (cc) "Have CBC and differential counts within the current reference ranges." (dd) "Healthy individuals selected should reflect the laboratory's patient population." (ee) "Separate reference ranges based on age may be necessary for pediatric or geriatric populations." (b) Sample Size: (a) "Select at least 25 to 50 samples." (b) "A larger sampling; however improves the confidence of the statistics generated from this study." (4) The surveyor asked the laboratory supervisor if the laboratory had a normal reference range for pediatric (Sysmex defines pediatric as less than 21 years of age) patients. The laboratory supervisor stated the laboratory did not have a separate reference range for pediatric patients but used the adult reference ranges for either male or female pediatric patients; (5) The surveyor explained to the laboratory supervisor the laboratory must have normal reference ranges appropriate for the patient population serviced by the laboratory; (6) The surveyor reviewed randomly selected CBC analyzer printouts from 3 months (October and December 2018; and July 2019) and identified 55 pediatric patients with CBC or H&H testing performed during the review period: (a) Patient #13: Age 5 - CBC testing was performed on 10 /01/18 (b) Patient #14: Age 3 - CBC testing was performed on 10/04/18 (c) Patient #15: Age 11 - CBC testing was performed on 10/05/18 (d) Patient #16: Age 5 - CBC testing was performed on 10/16/18 (e) Patient #17: Age 15 - CBC testing was performed on 10/22/18 (f) Patient #18: Age 18 - CBC testing was performed on 10/22 /18 (g) Patient #19: Age 2 - CBC testing was performed on 10/22/18 (h) Patient #20: Age 14 - CBC testing was performed on 10/29/18 (i) Patient #21: Age 14 - CBC testing was performed on 12/01/18 (j) Patient #22: Age 12 - CBC testing was performed on 12/01/18 (k) Patient #23: Age 6 - CBC testing was performed on 12/03 /18 (l) Patient #24: Age 18 - CBC testing was performed on 12/04/18 (m) Patient #25: Age 14 - CBC testing was performed on 12/06/18 (n) Patient #26: Age 15 - CBC testing was performed on 12/07/18 (o) Patient #27: Age 17 - CBC testing was performed on 12/11/18 (p) Patient #28: Age 3 - CBCtesting was performed on 12/11 /18 (q) Patient #29: Age 17 - CBC testing was performed on 12/12/18 (r) Patient #30: Age 4 - CBC testing was performed on 12/12/18 (s) Patient #31: Age 17 - CBC testing was performed on 12/14/18 (t) Patient #32: Age 17 - CBC testing was performed on 12/18/18 (u) Patient #33: Age 16 - CBC testing was performed on 12/18 /18 (v) Patient #34: Age 17 - CBC testing was performed on 12/21/18 (w) Patient #35: Age 17 - CBC testing was performed on 12/21/18 (x) Patient #36: Age 17 - CBC testing was performed on 12/21/18 (y) Patient #37: Age 13 - CBC testing was performed on 12/23/18 (z) Patient #38: Age 3 - CBC testing was performed on 12/26 /18 (aa) Patient #39: Age 11 months - CBC testing was performed on 12/26/18 (bb) Patient #40: Age 5 - H&H testing was performed on 12/27/18 (cc) Patient #41: Age 1 - H&H testing was performed on 12/31/18 (dd) Patient #42: Age 19 - CBC testing was performed on 07/03/19 (ee) Patient #43: Age 1 - H&H testing was performed on 07/03/19 (ff) Patient #44: Age 18 - CBC testing was performed on 07/04/19 (gg) Patient #45: Age 19 - CBC testing was performed on 07/10/19 (hh) Patient #46: Age 4

	- CBC testing was performed on 07/10/19 (ii) Patient #47: Age 19 - CBC testing was performed on 07/10/19 (jj) Patient #48: Age 1 month - CBC testing was performed on 07/13/19 (kk) Patient #49: Age 19 - CBC testing was performed on 07/16/19 (ll) Patient #50: Age 5 - CBC testing was performed on 7/16/19 (mm) Patient #51: Age 19 - CBC testing was performed on 07/17/19 (nn) Patient #52: Age 18 - CBC testing was performed on 07/17/19 (oo) Patient #53: Age 18 - CBC testing was performed on 07/21/19 (pp) Patient #54: Age 16 - CBC testing was performed on 07/24/19 (qq) Patient #55: Age 1 - H&H testing was performed on 07/24/19 (rr) Patient #56: Age 11 months - H&H testing was performed on 07/24/19 (ss) Patient #57: Age 19 - CBC testing was performed on 07/24/19 (tt) Patient #59: Age 9 days - H&H testing was performed on 07/25/19 (uu) Patient #60: Age 14 - CBC testing was performed on 07 /26/19 (vv) Patient #61: Age 18 - testing was performed on 07/26/19 (ww) Patient #62: Age 16 - testing was performed on 07/28/19 (xx) Patient #63: Age 15 - testing was performed on 07/28/19 (yy) Patient #64: Age18 - testing was performed on 07/30 /19 (zz) Patient #65: Age 10 - testing was performed on 07/30/19 (aaa) Patient #66: Age 11 months - H&H testing was performed on 07/30/19 (bbb) Patient #67: Age 16 months - H&H testing was performed on 07/30/19
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor and testing person #1, the laboratory failed to ensure expired Blood Bank testing materials were not used. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor the laboratory performed Crossmatch testing (i.e. ABO/Rh typing, Antibody Screen testing, DAT (Direct Antibody Testing), and Compatibility testing) using the tube method; (2) On the second day of the survey, the surveyor reviewed Blood Bank QC (Quality Control) and patient testing records from January 2018 through August 2019. Documentation showed the laboratory used expired testing materials for patient and QC testing. The findings follow: (a) Anti-B Reagent (Lot #V1786081) used for ABO testing, had a manufacturer's expiration date of 11/29/18. Documentation showed the reagent had been used on 6 days of patient testing: (i) 11/30/18, 12/04/18, and 12/07/18; (ii) On 12 /08/18, the expiration date of the reagent, Lot #V1786081, documented in the QC records was changed to "12/29/18." The laboratory supervisor and testing person #1 checked purchase records and verified the expiration date of Lot #V1786081 was 11 /29/18; (iii) The expired reagent was used on 12/08/18, 12/15/18, and 12/17/18 for patient and QC testing. (b) Reagent Red Blood Cells A1 (Lot #640618025), and Reagent Red Blood Cells B (Lot #640418025), which were used for ABO serum blood typing, had a manufacturer's expiration date of 01/26/19. Documentation showed the red blood cells had been used on 2 days of patient testing: 01/29/19 and 01 /31/19; (c) Screen Cells I and Screen Cells II (Lot #543118025), which were used for Antibody Screen testing, had a manufacturer's expiration date of 01/26/19 and had been used on 2 days of patient testing: 01/29/19 and 01/31/19; (d) Check Cells (Lot #643218025) used as quality control for DAT, had a manufacturer's expiration date of 01/26/19 had been used on 2 days of patient testing: 01/29/19 and 01/31/19. (3) The surveyor reviewed the records with the laboratory supervisor and testing person #1

	who stated to the surveyor expired reagents had been used, as listed above; (4) Examples of patient testing performed when the laboratory used the expired testing materials listed above, follow: (a) Patient #2 - Crossmatch testing performed on 11/30 /18 (b) Patient #3 - ABO typing and Antibody Screen testing performed on 12/04/18 (c) Patient #4 - Crossmatch testing performed on 12/07/18 and 12/08/18 (d) Patient #5 - ABO typing and Antibody Screen testing performed on 12/15/18 (e) Patient #6 - ABO typing and Antibody Screen testing performed on 12/17/18 (f) Patient #7 - ABO typing and Antibody Screen testing performed on 12/17/18 (g) Patient #8 - Crossmatch testing performed on 12/17/18 (h) Patient #9 - Crossmatch testing performed on 12/17/18 (i) Patient #10 - Crossmatch testing performed on 01/29/19 (j) Patient #11 - Crossmatch testing performed on 01/31/19 (k) Patient #12 - Crossmatch testing performed on 01/31/19
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 laboratory supervisor, the laboratory failed to perform maintenance procedures as required by the manufacturers. Findings include: SYSMEX CA 620 (1) On the first day of the survey, the laboratory supervisor stated to the surveyor PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed on the Sysmex CA 620 analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance instructions for the analyzer. The manufacturer required each week the instrument interior and exterior be cleaned; (3) The surveyor then reviewed the laboratory's maintenance records for 12 months (March, April, May, August, September, and December 2018; January, February, March, April, May, and June 2019) and identified the manufacturer's required weekly maintenance had not been documented as having been performed during 3 of the 12 months reviewed, as follows: (a) Between 01/21/19 and 02/04/19 (b) Between 06/10/19 and 06/24/19 (4) The surveyor reviewed the records with the laboratory supervisor who stated there was no documentation the maintenance procedure listed above had been performed as required. BECKMAN COULTER AU480 (1) On the first day of the survey, the laboratory supervisor stated to the surveyor chemistry electrolyte testing (Carbon Dioxide, Chloride, Potassium, and Sodium) was performed on the ISE (Ion-Selective Electrode) component of the Beckman Coulter AU480 analyzer; (2) On the third day of the survey, the surveyor reviewed the manufacturer's maintenance instructions for the analyzer. The manufacturer required the following maintenance procedures before performed: (a) Daily: (i) Check the buffer Syringe for Leaks (ii) ISE Cleaning (iii) Perform Serum Calibration (3) The surveyor reviewed maintenance records from January, February, November, and December 2018; and February, April, May, June, and July 2019 and identified the laboratory failed to perform the Daily maintenance procedures as required by the manufacturer. The maintenance procedures had not been documented as having been performed during 3 of the 9 months reviewed, as follows: (a) 02/24/19 (b) 04/15/19 (c) 06/22/19 (4) The surveyor reviewed the findings with the laboratory

	supervisor who stated to the surveyor, there was no documentation the required daily maintenance procedures had been performed on the days listed above. NOTE: D5429 was cited at the previous recertification survey performed 09/25/17-09/27/17.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory supervisor, the laboratory failed to ensure the urine centrifuge functioned properly. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor urine sediment examinations were performed in the laboratory. Patient urine specimens were processed in the Drucker Horizon 642VE centrifuge at a speed of 2000 RPM (Revolutions Per Minute) for 5 minutes; (2) The surveyor reviewed the policy titled "Laboratory Centrifuge Procedure." It stated "The maintenance is performed annually. The Drucker Horizon 642 VE time and rpm is 5 min at 2000 rpm for urine microscopy tests."; (3) The surveyor reviewed the centrifuge maintenance records for 2018 and 2019 and identified the centrifuge function checks had not been performed at the time and at the speed that patient urine samples were centrifuged for microscopic examinations, as follows: (a) 08/09/18: (i) The time was not checked at 5 minutes, but checked at 10 minutes; (ii) The speed was not checked at 2000 RPM, but checked at 3800 RPM. (b) 08/05/19: (i) The speed was not checked at 2000 RPM, but checked at 3700 RPM and 2500 RPM. (4) The surveyor reviewed the findings with the laboratory supervisor. The laboratory supervisor stated in 2019, the centrifuge had been checked at 2000 RPM but the biomedical technician failed to document the results. The laboratory supervisor also stated in 2018 the centrifuge had not been checked at the time and speed used to process urine samples for microscopic examinations.
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 laboratory supervisor and testing person #1, the laboratory failed to have control procedures that monitored the accuracy of the analytic process. Findings include: (1) On the first day of the survey, the laboratory supervisor stated the following to the surveyor: (a) Glucose testing was performed using the Beckman Coulter AU480 analyzer; (b) Three levels of BioRad Liquid Unassayed Multiqual Chemistry control materials (Level 1, Level 2, and Level 3) were performed each day of patient chemistry testing. (2) The surveyor reviewed QC (Quality Control) records (i.e., Levey Jennings graphs) for testing performed from 7 months-March, and November 2018; February, April, June, July, and August 2019. The surveyor identified 6 QC lot numbers were used during the review period. For 3 of the 6 QC lot numbers reviewed, the glucose results exhibited biases (the control results were consistently above or below the established mean) as follows: (a) 06/01 /19-06/30/19: (i) Level 1, Lot #56611: (aa) 18 of 30 control results were above the mean (ii) Level 2, Lot #56612: (aa) 25 of 29 control results were above the mean (iii) Level 3, Lot #56613: (aa) 26 of 29 control results were above the mean (b) 07/01/19-07/31/19: (i) Level 1, Lot #56611: (aa) 12 of 31 control results were above the mean (bb) 13 of 31 control results were below the mean (ii) Level 2, Lot #56612: (aa) 12 of 31 control results were above the mean (bb) 14 of 31 control results were below the mean (iii) Level 3, Lot #56613: (aa) 11 of 31 control results were above the mean (bb) 16 of 31 control results were below the mean (c) 08/01/19-08/29/19: (i) Level 1, Lot #56611: (aa) 2 of 22 control results were above the mean (bb) 18 of 22 control results were below the mean (ii) Level 2, Lot #56612: (aa) 2 control results were above the mean (bb) 18 control results were below the mean (iii) Level 3, Lot #56613: (aa) 20 of 22 control results were above the mean (3) There was no evidence in the records that the control biases had been identified and addressed; (4) The surveyor reviewed the records with the laboratory supervisor and testing person #1 and asked if there was documentation to prove the biases had been identified and addressed. The laboratory supervisor and testing person #1 stated the biases had not been identified and addressed; (5) Therefore, the surveyor determined the laboratory failed to have control procedures that monitored the accuracy of glucose testing for the time period listed above; (6) An example of patient testing performed when the laboratory failed to identify and evaluate the shift in glucose QC results: Patient #1-Testing performed on 07/22/19.
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 laboratory supervisor, the laboratory failed to follow the manufacturer's specifications for control materials. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor the laboratory used the Beckman Coulter Access II Immunoassay analyzer to perform CKMB (Creatinine Kinase isoenzyme) and Troponin I testing; (2) The laboratory supervisor also stated to the surveyor the laboratory tested three levels (Level 1, Level 2, and Level 3) of BioRad Liquichek

	Cardiac Markers Plus Control materials each day of testing to monitor the acceptability of testing. The QC (Quality Control) materials in use during the survey were Level 1-Lot #29881, Level 2-Lot #29882, and Level 3-Lot #29883; (3) On the third day of the survey, the surveyor reviewed the manufacturer's instructions (package insert) for the QC materials. Under "Assignment of Values" it stated, "The mean values and corresponding +/- 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are lot specific for this lot of product. Data from Unity Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides."; (4) The surveyor then reviewed QC records for 6 lot numbers used from 01/01/19 through 08 /30/19. The surveyor identified the laboratory utilized the manufacturer's mean and assay limits from the package insert of the BioRad Liquichek Cardiac Markers Plus Control QC materials and did not follow the manufacturer's specifications to establish its own mean and limits of acceptability, for 3 of the 6 QC lot numbers used from 04 /01/18-06/30/18: (a) Level 1, Lot #29871 (b) Level 2, Lot #29872 (c) Level 3, Lot #29873 (5) The surveyor reviewed the findings with the laboratory supervisor who stated to the surveyor, the laboratory used the package insert means and limits for the 3 lot numbers of QC materials listed above, and failed to follow the manufacturer's specifications to establish its own means and limits.
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, policies and procedures, manufacturer's instructions, and interview with the laboratory supervisor and testing person #1, 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 because of the following issues identified during the survey: (a) The laboratory failed to ensure the manufacturer's specifications were followed for coagulation and hematology testing. Refer to D5411; (b) The laboratory failed to ensure maintenance procedures were performed as required by the manufacturer. Refer to D5429; (c) The laboratory failed to ensure the function check protocol verified the urine centrifuge functioned properly. Refer to D5435; (d) The laboratory failed to have control procedures that monitored the accuracy and precision of the testing process. Refer to D5441; (e) The laboratory failed to follow the manufacturer's specifications for quality control materials. Refer to D5479.
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 laboratory supervisor and testing person #1, the laboratory director failed to provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: (1) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results. Refer to D6014; (2) The laboratory director failed to ensure the laboratory established and maintained a quality assessment program to assure the quality of laboratory services provided by the laboratory. Refer to D6021.
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 laboratory supervisor and testing person #1, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results. Findings include: (1) The laboratory director failed to ensure the laboratory followed the manufacturer's instructions. Refer to D5411; (2) The laboratory director failed to ensure maintenance procedures were performed as required by the manufacturer. Refer to D5429.
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, policies and procedures, and interview with the laboratory supervisor and testing person #1, 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.
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, policies and procedures, and interview with the laboratory supervisor and testing person #1, 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 the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042.
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, policies and procedure, and interview with the laboratory supervisor and testing person #1, 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 manufacturer's specifications were followed for coagulation and hematology testing. Refer to D5411; (2) The technical consultant failed to ensure maintenance procedures were performed as required by the manufacturer. Refer to D5429.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor and testing person #1, the laboratory director failed to provide overall management and direction in accordance with 493.1445 of this subpart. Findings include: (1) 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 D6087.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)

	The laboratory director must ensure that 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 laboratory supervisor and testing person #1, 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 expired testing materials had not been used for Imunohematology testing. Refer to D5417.