Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1036892	02/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Drumright Community Hospital, Llc	610 West Bypass, Drumright, 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 02/20/19-02/22/19. The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager at the conclusion of the survey.
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 manager, 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 proficiency testing records and identified the following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program): (a) First 2018 Chemistry Core Event (i) Chloride: 3 of 5 results exhibited a Positive bias (aa) CH-03: SDI 3.1 (bb) CH-04: SDI 3.0 (cc) CH-05: SDI 2.8 (b) Third 2018 Chemistry Core Event: (i) Vancomycin: 3 of 5 results exhibited a Negative bias (aa) CH-11: SDI -2.4 (bb) CH-14: SDI -2.2 (cc) CH-15: SDI -2.3 (c) First 2018 Hematology/Coagulation Event: (i) Hematocrit: 3 of 5 results exhibited a Positive bias (aa) PNT-02: SDI 2.6 (bb) PNT-03: SDI 2.2 (cc) PNT-05: SDI 2.4 (ii) MCHC (Mean Corpuscular Hemoglobin Concentration): 4 of 5 results exhibited a Negative bias (aa) PNT-01: SDI -2.7 (bb) PNT-02: SDI -3.0 (cc) PNT-04: SDI -2.3 (dd) PNT-05: SDI -2.4 (d) Third 2018 Hematology/Coagulation Event (i) RBC (Red Blood Count): 3 of 5 results exhibited a Negative bias (aa) PNT-12: SDI -1.8 (bb) PNT-13: SDI -2.7 (cc) PNT-14: SDI -2.3 (ii) Hematocrit: 3 of 5 results exhibited a Negative bias (aa) PNT-12: SDI -2.1 (bb) PNT-13: SDI -2.7 (cc) PNT-14: SDI -2.2 (iii) MCH (Mean Corpuscular Hemoglobin): 4 of 5 results exhibited a Positive bias (aa) PNT-11: SDI 2.2 (bb) PNT-12: SDI 2.0 (cc) PNT-13: SDI 3.0 (dd)

	PNT-14: SDI 2.8 (iv) MCHC: 4 of 5 results exhibited a Positive bias (aa) PNT-11: SDI 2.1 (bb) PNT-12: SDI 2.4 (cc) PNT-13: SDI 3.7 (dd) PNT-13: SDI 3.5 (v) Lymphocytes: 3 of 5 results exhibited a Positive bias (aa) PNT-11: SDI 2.2 (bb) PNT-12: SDI 2.1 (cc) PNT-14: 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, and there was no documentation the laboratory took corrective action (e.g., reviewed quality control, maintenance records, calibration, if patient results had been affected, etc.) for the biases; (3) The surveyor reviewed the findings with the laboratory manager who stated to the surveyor the laboratory had not identified or evaluated the biases, and corrective action had not been taken. NOTE: D5211 was cited at the previous recertification survey performed 05/31/17-06/02/17.
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, and interview with the laboratory manager, the laboratory failed to ensure the manufacturer's environmental specifications were met. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the Beckman Coulter AU480 chemistry analyzer was put into use on 10/08/17. Examples of the testing performed included Acetaminophen, Alcohol, Digoxin, Dilantin, Albumin, Ammonia, Amylase, CK (Creatinine Kinase), Glucose, HDL (High Density Lipoprotein), Lipase, Magnesium, Uric Acid, Total Bilirubin, Total Cholesterol, etc; (2) On the second day of the survey, the surveyor reviewed the manufacturer's environmental requirements. The manufacturer required a humidity between 40 and 80%; (3) The surveyor then reviewed the laboratory humidity records from 01/01/18 through 02/21/19. The surveyor identified on 232 of the 417 days reviewed, the manufacturer's humidity requirement had not been met, or the humidity had not been documented. The specific findings follow: (a) January 2018: (i) On 22 of 31 days, the humidity was unacceptable: (aa) 11%: Days 17,25 (bb) 14%: Day 18,19 (cc) 16%: Days 15,16 (dd) 18%: Day 30 (ee) 20%: Days 12,13,23,24,29 (ff) 21%: Days 14,22,28,31 (gg) 22%: Days 11,27 (hh) 25%: Days 8,9 (ii) 28%: Day 10 (jj) 29%: Day 26 (ii) On 7 of 31 days, the humidity had not been documented: (aa) Days: 1,2,3,4,5,6,7 ("Lo" was written by the dates) (b) February 2018: (i) On 22 of 28 days, the humidity was unacceptable: (aa) 9%: Day 2 (bb) 13%: Days 7,8 (cc) 14%: Day 6 (dd) 15%: Day 4,21 (ee) 17%: Day 5 (ff) 18%: Day 11 (gg) 19%: Days 9,10 (hh) 20%: Days 3,12,13,20 (ii) 22%: Day 1 (jj) 24%: Day 16 (kk) 25%: Day 22,26 (ll) 26%: Day 23 (mm) 28%: Day 18 (nn) 29%: Days 17,24 (ii) On 1 of 28 days, the humidity was not documented: Day 25 (c) March 2018: On 27 of 31 days, the humidity was unacceptable: (i) 10%: Day 6 (ii) 15%: Day 7 (iii) 18%: Day 12 (iv) 20%: Day 13,14 (v) 21%: Day 2,5,22 (vi) 22%: Day 23 (vii) 23%: Days 1,15,21 (viii) 25%: Day 16 (ix) 26%: Day 17 (x) 27%: Day 8,18 (xi) 28%: Days 9,20 (xii) 29%: Days 11,24 (xiii) 30%: Day 3 (xiv) 32%: Day 25 (xv) 34%: Day 19 (xvi) 35%: Day 4 (xvii) 36%: Day

	29 (xviii) 38%: Days 28,30 (d) April 2018: On 27 of 30 days, the humidity was unacceptable: (i) 15%: Days 8,14 (ii) 16%: Day 7 (iii) 17%: Day 16 (iv) 20%: Days 5,15, (v) 22%: Days 19,20,21 (vi) 24%: Days 1,9,10 (vii) 26%: Day 18 (viii) 27%: Days 6,27 (ix) 28%: Days 4,29 (x) 30%: Day 2,28 (xi) 31%: Days 22,30 (xii) 33%: Day 24 (xiii) 34%: Days 3,25 (xiv) 36%: Days 17,23,26 (e) May 2018: On 3 of 31 days, the humidity was unacceptable (i) 36%: Day 3 (ii) 37%: Day 2 (iii) 38%: Day 1 (f) October 2018: On 11 of 31 days, the humidity was unacceptable (i) 26%: Days 16,21 (ii) 29%: Day 17 (iii) 31%: Day 18 (iv) 32%: Day 22 (v) 34%: Day 20 (vi) 35%: Days 15,23 (vii) 36%: Days 11,28 (viii) 39%: Day 25 (g) November 2018: On 30 of 30 days, the humidity was unacceptable (i) 11%: Days 13,14 (ii) 14%: Days 10,15 (iii) 15%: Day 26 (iv) 16%: Days 12,21 (v) 17%: Days 11,20,27 (vi) 19%: Day 24 (vii) 20%: Days 16,17,18,25,28 (viii) 21%: Day 19 (ix) 25%: Days 9,22 (x) 26%: Day 7 (xi) 27%: Days 2,23,30 (xii) 28%: Days 3,6,8 (xiii) 29%: Days 4,29 (xiv) 34%: Days 1,5 (h) December 2018: On 30 of 31 days, the humidity was unacceptable (i) 11%: Day 31 (ii) 12%: Days 9,10,30 (iii) 13%: Days 5,28 (iv) 14%: Day 29 (v) 15%: Day 8 (vi) 16%: Days 4,15,17,21,22 (vii) 17%: Days 16,23 (viii) 18%: Days 3,24 (ix) 19%: Days 2,6,7,20 (x) 20%: Day 11 (xi) 22%: Day 25 (xii) 26%: Day 1 (xiii) 28%: Days 12,13,14,18 (xiv) 30%: Day 26 (xv) 38%: Day 27 (i) January 2019: On 31 of 31 days, the humidity was unacceptable (i) 3%: Day 29 (ii) 10%: Day 20 (iii) 11%: Day 2 (iv) 12%: Days 1,8,28 (v) 13%: Day 26 (vi) 14%: Days 3,19 (vii) 15%: Days 21,22,27 (viii) 17%: Days 9,13,14 (ix) 19%: Day 4 (x) 20%: Days 16,23,24 (xi) 21%: Days 5,11,12,30,31 (xii) 22%: Days 15,25 (xiii) 23%: Day 10 (xiv) 26%: Days 6,7 (xv) 27%: Day 17 (xvi) 30%: Day 18 (j) February 2019: On 21 of 21 days, the humidity was unacceptable (i) 5%: Day 9 (ii) 11%: Day 7 (iii) 16%: Day 10 (iv) 18%: Days 12,21 (v) 20%: Days 8,17,19,20 (vi) 21%: Days 14,16,18 (vii) 23%: Days 6,15 (viii) 25%: Day 5 (ix) 26%: Days 4,13 (x) 28%: Day 11 (xi) 30%: Day 3 (xii) 35%: Day 2 (xiii) 36%: Day 1 (4) The surveyor reviewed the findings with the laboratory manager. The laboratory manager stated to the surveyor the laboratory failed to ensure the manufacturer's humidity requirement for the Beckman Coulter AU480 chemistry analyzer had been met as listed above. NOTE: D5413 was cited at the previous recertification survey performed 05/31/17-06/02/17.
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 the laboratory manager, the laboratory failed to verify the reference intervals used with new test system were appropriate for the laboratory's patient population. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the Beckman Coulter AU480 chemistry analyzer was put into use on 10/08/17. Examples of the testing performed included Acetaminophen, Alcohol, Digoxin, Dilantin, Albumin, Ammonia, Amylase, CK (Creatinine Kinase), Glucose, HDL (High Density Lipoprotein), Lipase, Magnesium, Uric Acid, Total Bilirubin, Total Cholesterol, etc; (2) The surveyor

	reviewed the validation records for the new analyzer and could not find documentation whether the reference intervals (normal ranges) had been established by the laboratory or if the laboratory verified the manufacturer's reference intervals. The surveyor asked the laboratory manager how the laboratory determined the reference ranges being used with the new analyzer. The laboratory manager stated to the surveyor, the laboratory used the manufacturer's normal reference ranges for each analyte tested on the analyzer; (3) The surveyor asked the laboratory manager if the laboratory verified the reference intervals as appropriate for the patient population the laboratory serviced. The laboratory manager stated to the surveyor the laboratory did not verify the reference ranges being used for patient testing on the new analyzer.
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 manager, the laboratory failed to perform maintenance procedures as required by the manufacturer. Findings include: BECKMAN COULTER ACCESS 2 IMMUNOASSAY ANALYZER (1) On the first day of the survey, the laboratory manager stated to the surveyor the Beckman Coulter Access 2 Immunoassay analyzer was put into use on 09/07/17 to perform Troponin I testing; (2) The surveyor reviewed the manufacturer's weekly maintenance instructions for the analyzer as included on the Access 2 System Maintenance Log, which were: (a) Clean Instrument Exterior (b) Inspect Liquid Waste Bottle (c) Check Waste Filter Bottle (d) Inspect/Clean Primary Probe (e) Replace/Clean Aspirate Probes (f) Run Daily Maintenance (g) Run System Check (3) Maintenance records from 16 months (October 2017 through January 2019) were reviewed by the surveyor. The surveyor identified the weekly maintenance had not been documented as performed during 11 weeks of the period reviewed. The findings follow: (a) Between 01/20/18 and 01/29/18 (b) Between 01/29/18 and 02/12 /18 (c) Between 02/20/18 and 03/05/18 (d) Between 03/21/18 and 04/03/18 (e) Between 04/17/18 and 04/30/18 (f) Between 06/08/18 and 06/19/18 (g) Between 07/13 /18 and 07/27/18 (h) Between 08/17/18 and 08/31/18 (i) Between 09/14/18 and 09/25 /18 (j) Between 11/16/18 and 11/29/18 (k) Between 12/21/18 and 01/01/19 (4) The surveyor reviewed the findings with the laboratory manager who stated to the surveyor there was no documentation the manufacturer's required weekly maintenance procedures had been performed, as listed above. BECKMAN COULTER AU480 ANALYZER (1) On the first day of the survey, the laboratory manager stated to the surveyor the Beckman Coulter AU480 chemistry analyzer was put into use on 10/08 /17. Examples of the testing performed included Acetaminophen, Alcohol, Digoxin, Dilantin, Albumin, Ammonia, Amylase, CK (Creatinine Kinase), Glucose, HDL (High Density Lipoprotein), Lipase, Magnesium, Uric Acid, Total Bilirubin, Total Cholesterol, etc; (2) The surveyor reviewed the manufacturer's weekly maintenance instructions for the analyzer as included on the AU 480 Maintenance Log, which were: (a) Clean Sample Pre-Dilution Bottle (b) Perform a W2 (i.e. automatic wash of the probes, mix bars and cuvettes) (c) Perform a Photocal (3) Maintenance logs from October 2017 through January 2019 were reviewed. The surveyor identified the weekly maintenance had not been performed during 1 of the 16 months reviewed: (a) Between 12/25/17 and 01/09/18 (4) The surveyor reviewed the findings with the

	laboratory manager who stated to the surveyor there was no documentation on the logs which proved the manufacturer's required weekly maintenance procedures had been performed, as listed above. ROCHE OPTI-CCA-TS BLOOD GAS ANALYZER (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory performed blood gas testing (i.e. pH, pO2, pCO2) using the Roche Opti-CCA-TS blood gas analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirement for the analyzer. The manufacturer required the peristaltic pump and gas I/O Port be replaced on an annual basis to assure the analyzer operated at peak performance; (3) The surveyor reviewed maintenance records for the analyzer from October 2017 through December 2018 and identified the annual maintenance had not been performed in October 2018 as required. The surveyor asked the laboratory manager why the annual maintenance had not been performed in October 2018 as required. The laboratory manager explained the laboratory could not obtain the peristaltic pump and I/O port component until December 2018 due to financial issues; (4) The surveyor reviewed the manufacturer's maintenance requirement with the laboratory manager, who stated to the surveyor the laboratory did not perform the manufacturer's annual maintenance procedure as required to ensure the analyzer worked properly. NOTE: D5429 was cited at the previous recertification survey performed 05/31/17-06/02/17.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to perform calibration verification procedures at least once every 6 months. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the Beckman Coulter AU480 chemistry analyzer was put into use on 10/08/17. Examples of the testing performed included Acetaminophen, Alcohol, Digoxin, Dilantin, Albumin, Ammonia, Amylase, CK (Creatinine Kinase), Glucose, HDL (High Density Lipoprotein), Lipase, Magnesium, Uric Acid, Total Bilirubin, Total Cholesterol, etc; (2) The surveyor reviewed calibration verification

	records for the testing (since routine calibration procedures were performed using less than three calibrators for the analytes, calibration verification procedures, using three or more levels of calibration materials, were required every 6 months). There was no evidence that calibration verification procedures had been performed for the analytes between 10/2017 and 12/2018 (Calibration verification was due in 04/2018). (3) The surveyor asked the laboratory manager if additional calibration verification procedures had been performed between 10/2017 and 12/2018. The laboratory manager stated calibration verification procedures had not been performed in 04/2018 because the calibration materials could not be obtained for the 6 month calibration verification because of financial issues. NOTE: D5439 was cited at the previous recertification survey performed 05/31/17-06/02/17.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to establish statistical parameters for unassayed Protime control materials. Findings include (1) On the first day of the survey, the laboratory manager stated the following: (a) The Hemochron Jr. Signature + analyzer was used to perform PT (Prothrombin Time) testing using the Citrate PT cuvettes; (b) directCHECK Citrate PT Normal and Abnormal controls were tested on new cuvette lot numbers and each month. (2) The surveyor reviewed the manufacturer's instructions (package insert) for the quality control materials. The inserts did not contain statistical parameters (i.e., means, standard deviations, etc.) for evaluating PT control results, verifying the controls were unassayed; (3) The surveyor then reviewed quality control records from December 2017 through January 2019 and identified 5 QC lot numbers had been used during the review period. For 1 of the 5 lot numbers (Abnormal, Lot #J7DAC009 (used from 06/29/18-01/30/19), the records showed the laboratory established acceptable limits of 43.7-56.9. However, the limit listed on the laboratory's QC log was 36.0-62.0, which was the manufacturer's limit for the QC lot number; (4) The surveyor reviewed the findings with the laboratory manager, who stated to the surveyor, the laboratory failed to use the QC limits established by the laboratory as required by the manufacturer, but instead used the manufacturer's QC limits. NOTE D5469 was cited at the previous recertification survey performed 05/31/17-06/02/17.
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, manufacturers' instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's specifications for control materials. Findings include: BIO-RAD LIQUID ASSAYED MULTIQUAL CONTROL MATERIALS (1) On the first day of the survey, the laboratory manager stated to the surveyor the Beckman Coulter AU480 chemistry analyzer was put into use on 10/08/17. Examples of the testing include the following: Albumin, Digoxin, CK (Creatinine Kinase), Glucose, Magnesium, Uric Acid, Total Bilirubin, Total Cholesterol, etc.; (2) The laboratory manager also stated to the surveyor, the laboratory used 2 levels (Level 1 and Level 3) of Bio-Rad Liquid Assayed Multiqual control materials each day of patient testing to monitor acceptability of the testing; (3) The surveyor reviewed the manufacturer's instructions (package insert) for the QC (Quality Control) 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 the QC records from October 2017 through January 2019 for the 6 lot numbers used since the analyzer was put into use. The surveyor identified the laboratory utilized the manufacturer's mean and assay limits from the QC package insert for 6 of the 6 lot numbers used and did not establish its own mean and limits of acceptability as required in the manufacturer's specifications. The lot numbers were: (a) Level 1, Lot #45781 and Level 3, Lot #45783: Used from 10/01/17-02/28/18 (b) Level 1, Lot #45791 and Level 3, Lot #45793: Used from 02/29/18-09/26/18 (c) Level 1, Lot #45801 and Level 3, Lot #45803: Used from 09/27/18 through 02/20/19 (5) The surveyor reviewed the findings with the laboratory manager who stated to the surveyor, the laboratory used the package insert means and limits for the QC materials listed above, and failed to follow the manufacturer's specifications to establish its own means and limits. BIO-RAD LIQUICHEK IMMUNOASSAY + CONTROL MATERIALS (1) The laboratory manager stated to the surveyor the laboratory performed Vancomycin testing using the Beckman Coulter AU480 analyzer; (2) The laboratory manager also stated to the surveyor, the laboratory used 2 levels (Level 1 and Level 3) of Bio-Rad LiquiChek Immunoassay + control materials each day of patient testing; (3) 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 from

	April 2018 through January 2019 and identified 4 QC lot numbers were used during the review period: (a) Level 1, Lot #40961 and Level 3 Lot #40963: Used from 04/23 /18-12/31/18 (b) Level 1, Lot #40931 and Level 3, Lot #40933: Used from 01/01/19 through the survey (5) The surveyor identified for 2 of the 4 lot numbers (Lot #40961 and Lot #40963), the laboratory utilized the manufacturer's mean and assay limits from the package insert and did not follow the manufacturer's specifications to establish its own mean and limits of acceptability; (6) The surveyor reviewed the findings with the laboratory manager who stated to the surveyor, the laboratory used the package insert means and limits for the 2 lot numbers of QC materials listed above, and failed to follow the manufacturer's specifications to establish its own means and limits. PROTHROMBIN TIME CONTROL MATERIALS (1) On the first day of the survey, the laboratory manager stated the following: (a) The Hemochron Jr. Signature + analyzer was used to perform INR (International Normalized Ratio) testing using the Citrate PT cuvettes; (b) directCHECK Citrate PT Normal and Abnormal controls were tested on new cuvette lot numbers and each month. (2) On the second day of the survey, the surveyor reviewed the manufacturer's instructions (package inserts) for the control materials which stated, "ITC recommends that each institution establish its own expected range of response based on the mean +/- 2 standard deviations of at least 20 repeated test results. The local mean values established should fall within the manufacturer's acceptable performance range"; (3) The surveyor then reviewed QC records from December 2017 through January 2019. For 1 of the 5 lot numbers of QC materials used during the review period, the laboratory failed to follow the manufacturer's instructions. With Citrate Normal Control, Lot# G8DNC007 (Put into use on 01/04/19 and in use during the survey), the laboratory used 11 replicates instead of 20 as the manufacturer instructed; (4) The surveyor reviewed the findings with the laboratory manager who stated to the surveyor the laboratory had not followed the manufacturer's instructions for establishing quality control ranges. NOTE: D5479 was cited at the previous recertification survey performed 05/31/17-06/02/17.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to take corrective action when the manufacturer's environmental specifications had not been met. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the Beckman Coulter AU480 chemistry analyzer was put into use on 10/08/17. Examples of the testing performed, included the following: Acetaminophen, Alcohol, Digoxin, Dilantin, Albumin, Ammonia, Amylase, CK (Creatinine Kinase), Glucose, HDL (High Density Lipoprotein), Lipase, Magnesium, Uric Acid, Total Bilirubin, Total Cholesterol, etc; (2) The surveyor reviewed the manufacturer's environmental requirements. The manufacturer required a humidity between 40 and 80%; (3) The surveyor then reviewed the laboratory humidity records from 13 months (January 2018 through the survey). The surveyor identified on 232 of the 386 days reviewed, the manufacturer's humidity requirement had not been met, or the humidity had not been documented. The specific findings follow: (a) January 2018: (i) On 22 of 31

	days, the humidity was lower than 40%: Days 8,9,10,11,12,13,14,15,16,17,18, 19,22,23,24,25,26 27,28,29,30,31; (ii) On 7 of 31 days, the humidity had not been documented: Days 1,2,3,4,5,6,7 ("Lo" was written by the dates); (iii) There was no documentation corrective action (i.e. turn on humidifier, recheck humidity, re-train testing personnel, etc.) had been taken for the unacceptable humidity or the undocumented humidity. (b) February 2018: (i) On 22 of 28 days, the humidity was lower than 40%: Days 1,2,3,4,5,6,7,8,9,10,11,12,13,16, 17,18,20,21,22,23,24,26; (ii) On 1 of 28 days, the humidity was not documented: Day 25; (iii) There was no documentation corrective action had been taken for the unacceptable humidity or the undocumented humidity. (c) March 2018: (i) On 27 of 30 days, the humidity was lower than 40%: Days 1,2,3,4,5,6,7,8,9,11,12,13,14, 15,16,17,18,19,20,21,22,23,24,25,28,29,30; (ii) There was no documentation corrective action had been taken for the unacceptable humidity. (d) April 2018: (i) On 27 of 30 days, the humidity was lower than 40%: Days 1,2,3,4,5,6,7,8,9,10,14,15,16, 17,18,19,20,21,22,23,24,25,26,27,28,29,30; (ii) There was no documentation corrective action had been taken for the unacceptable humidity (e) May 2018: (i) On 3 of 31 days, the humidity was lower than 40%: Days 1,2,3 (ii) There was no documentation corrective action had been taken for the unacceptable humidity. (f) October 2018: (i) On 11 of 31 days, the humidity was lower than 40%: Days 11,15,16,17,18,20,21,22,23, 25,28; (ii) There was no documentation corrective action had been taken for the unacceptable humidity. (g) November 2018: (i) On 30 of 30 days, the humidity was unacceptable: Days 1,2,3,4,5,6,7,8 9,10,11,12, 13,14,15, 16,17,18,19,20,21,22,23,24,25,26,27 ,28,29,30; (ii) There was no documentation corrective action had been taken for the unacceptable humidity. (h) December 2018: (i) On 30 of 31 days, the humidity was lower than 40%: Days 1,2,3,4,5,6,7,8,9,10,11,12,13, 14,15,16,17,18,20,21,22,23,24,25,26,27, 28,29,30,31; (ii) There was no documentation corrective action had been taken for the unacceptable humidity. (i) January 2019: (i) On 31 of 31 days, the humidity was lower than 40%: Days 1,2,3,4,5,6,7,8,9, 10,11,12,13,14,15,16,17,18,19,20,21, 22,23,24,25,26,27,28,29,30,31; (ii) There was no documentation corrective action had been taken for the unacceptable humidity. (j) February 2019: (i) On 21 of 21 days, the humidity was lower than 40%: Days 1,2,3,4,5,6,7,8,9,10,11,12,13, 14,15,16,17,18,19,20,21; (ii) There was no documentation corrective action had been taken for the unacceptable humidity. (4) The surveyor reviewed the findings with the laboratory manager, who stated to the surveyor the laboratory had not taken corrective action for the days listed above when the humidity had not been documented.
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 laboratory manager, the laboratory failed to have an ongoing mechanism for performing effective analytice assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment due to the following issues identified during the survey: (a) The laboratory failed to ensure the manufacturer's environmental specifications were met. Refer to

	D5413; (b) The laboratory failed to demonstrate the performance specifications for a new test system. Refer to D5421; (c) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (d) The laboratory failed to perform calibration verification procedures at least once every 6 months. Refer to D5439; (e) The laboratory failed to establish statistical parameters for unassayed control materials. Refer to D5469; (f) The laboratory failed to follow the manufacturer's specifications for establishing quality control ranges. Refer to D5479.
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 manager, 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 manufacturer's environmental specifications were met. Refer to D5413. NOTE: D6014 was cited at the previous recertification survey performed 05/31/17-06/02/17.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director failed to ensure proficiency testing reports were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings include: (1) The laboratory director failed to ensure biases obtained on proficiency testing had been identified and evaluated. Refer to D5211.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory director failed to ensure a quality control program was established and maintained to assure the quality of laboratory services provided by the laboratory. Findings include: (1) The laboratory director failed to ensure maintenance procedures were performed and documented. Refer to D5429; (2) The laboratory director failed to ensure calibration verification procedures were performed at least once every 6 months. Refer to D5439; (3) The laboratory director failed to ensure to statistical parameters for unassayed Protime control materials were established. Refer to D5469; (4) The laboratory director failed to follow the manufacturer's specifications for control materials. Refer to D5479; (5) The laboratory director failed to ensure corrective action was taken when the manufacturer's specifications had not been met. Refer to D5785. NOTE: D6020 was cited at the previous recertification survey performed 05/31/17-06/02/17.
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, and interview with the laboratory manager, the laboratory failed to ensure an effective quality assessment program had been established and maintained to assure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure the laboratory had an effective quality assessment program due to the issues identified during the survey. Refer to D5791. NOTE: D6021 was cited at the previous recertification survey performed 05/31/17-06/02/17.
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 the laboratory manager, 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.