Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2065718	10/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Little River Healthcare-Central Texas Llc	806 N Crockett, Cameron, TX	

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	As a result of the CLIA recertification inspection conducted on October 9, 2018 and October 10, 2018, the laboratory is not in compliance with the following Conditions of Participation required for certification in the CLIA program at 42 CFR part 493: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant;
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the Contour Glucose meter operator's manual, laboratory policy, review of patient records, and interview with facility personnel, the laboratory failed to follow the manufacturer's instructions for use of the analyzer for 3 of 13 patients reviewed on October 10, 2018. The findings included: 1. Based on review of the Ascensia Diabetes Care Contour Blood Glucose Monitoring System (Rev. 05/16), the manual states the following: " The CONTOUR blood glucose monitoring system is intended for self-testing by people with diabetes to monitor glucose concentrations in whole blood. The CONTOUR system is not intended for the diagnosis of or screening for diabetes mellitus." 2. Based on review of the laboratory's policy "Glucometer Procedure" (Date Developed: Aug-13, Date Revised: Nov-15, Approved: Dec-15), the policy states: "PURPOSE: To obtain a quantitative measure of glucose in whole blood to diagnose hypoglycemia or hyperglycemia." 3. Based on a review of patient records from July 16, 2018 through October 7, 2018, thirteen (13) patients were identified as having orders for glucose testing by the Contour blood glucose monitoring system. Thirteen 13 patients identified to have order for glucose measurement by the Contour

	blood glucose monitoring system between July 16, 2018 and October 7, 2018: 833069 - Diagnosis of Diabetes present 963770 - No diagnosis of diabetes 833387 - Diagnosis of Diabetes present 1014939 - Order discontinued - No testing 866223 - Diagnosis of Diabetes present 863447 - Order discontinued - No testing 89816 - No diagnosis of diabetes 887244 - No diagnosis of diabetes 996412 - Diagnosis of Diabetes present 860656 - Diagnosis of Diabetes present 928884 - Diagnosis of Diabetes present 877745 - Diagnosis of Hyperglycemia 865757 - Diagnosis of Diabetes present Of the 13 patients identified: Three (3) patients were tested without a diagnosis of diabetes The order for 2 patients was discontinued and no blood glucose testing was performed with the Contour. Eight (8) patients had a diagnosis of diabetes or hyperglycemia. 4. In an interview at 14:56 hours on 10/09/2018, the Laboratory Manager and Chief of Nursing stated the Contour Glucose meter had been used by healthcare professionals to screen the glucose levels of patients who were not known to have a diagnosis that included diabetes and the meter had not been used for self-testing by people with diabetes as written in the intended use section of the operator's manual.
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 review of laboratory temperature records, hematology analyzer verification records, quality control records, calibration verification records, quality assessment records, and interview with facility personnel, the laboratory failed to meet the meet the applicable analytic systems requirements in 493.1251 through 493.1283 between December 2016 and September 2018. The findings included: 1. Based on surveyor observations, review of Siemens Dimension Creatine Kinase (CKI)/Creatine Kinase MB (MBI) calibrator instructions for storage, laboratory temperature records, and interview with facility personnel, the laboratory failed to store the Siemens Dimension CKI/MBI calibrators at the required temperature for 48 of 50 days between August 22, 2018 and October 10, 2018. Refer to D5413-I. Based on surveyor observations, review of Beckman Coulter hematology reagent instructions for storage, laboratory temperature records, and interview with facility personnel, the laboratory failed to store the Beckman Coulter reagents at the required temperature for 35 of 283 days between January 1, 2018 and October 10, 2018. Refer to D5413-II. 2. Based on a review of the laboratory's policies and procedures, the Beckman Coulter ActDiff 5 hematology analyzer verification study, random review of patient records, and interview with facility personnel, the laboratory failed to verify 5 of 5 analyte reference ranges reviewed prior to performing patient testing between May 23, 2017 and October 9, 2018. Refer to D5421. 3. Based on a review of laboratory policies and procedures, assay instructions for use, calibration verification records, and interview with facility personnel, the laboratory failed to perform calibration verification procedures at least every 6 months for 3 of 3 analytes over 3 of 3 six month spans between 12/30/2016 and October 10, 2018. Refer to D5439. 4. The laboratory failed to monitor the accuracy and precision over time for 4 of 4 lots of quality control materials used between January 11, 2017 and October 10, 2018 for the Opti-CCA

	blood gas analyzer. Deficiencies at 42 CFR 493.1256 Control Procedures were cited on the previous survey conducted on 11/03/2016. This is a repeat deficiency. Refer to D5441-I. 5. Based on review of laboratory policies and procedures, quality control records, and interview with facility personnel, the laboratory failed to monitor the accuracy and precision over time for 13 of 13 lots of quality control materials used between January 31, 2017 and October 10, 2018 to monitor the performance of the Cardiac Panel and D-Dimer Panel tested on the Alere Triage analyzer. Refer to D5441-II. Deficiencies at 42 CFR 493.1256 Control Procedures were cited on the previous survey conducted on 11/03/2016. This is a repeat deficiency. Refer to D5441-II. 6. Based on review of the Bio-Rad Lyphochek Immunoassay Plus Control Levels 1, 2, and 3 and Liquid Assayed Multiqual 1,2,3 instructions for use, laboratory quality control records, and interview with facility personnel, the laboratory failed to establish acceptability criteria for 6 of 6 lots of control material in use between November 20, 2017 and October 10, 2018. Deficiencies at 42 CFR 493.1256 Control Procedures (D5469) were cited on the November 10, 2016 inspection. This is a repeat deficiency. Refer to D5469. Deficiencies at 42 CFR 493.1250 Analytic Systems were cited on the previous survey conducted on 11/03/2016. This is a repeat deficiency.
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: I. Based on surveyor observations, review of Siemens Dimension Creatine Kinase (CKI)/Creatine Kinase MB (MBI) calibrator instructions for storage, laboratory temperature records, and interview with facility personnel, the laboratory failed to store the Siemens Dimension CKI/MBI calibrators at the required temperature for 48 of 50 days between August 22, 2018 and October 10, 2018. The findings included: 1. At 14:16 hours on 10/10/2018 in the laboratory, the surveyor observed two boxes of Siemens Dimension Creatine Kinase (CKI)/Creatine Kinase MB (MBI) calibrators stored in the door of Freezer 1. 2 boxes Lot 8DD006 Expiration: 2019-05-01 In handwriting, both boxes were marked as received on 8/22/2018. 2. Based on review of the Siemens Dimension Creatine Kinase (CKI)/Creatine Kinase MB (MBI) calibrator instructions for use (REF DC32), under Storage, the document states the following: "Unopened vials must be stored frozen at -25 Celsius to -15 Celsius". 3. Based on review of review of the laboratory's freezer temperature records, the laboratory defined the acceptable temperature range as -10 Celsius to -30 Celsius. The recorded temperatures were outside of the -25 to -15 Celsius required for storage of the Siemens Dimension Creatine Kinase (CKI)/Creatine Kinase MB (MBI) calibrators on 48 of 50 days. Date Temperature 22-Aug-18 -13.5 23-Aug-18 -13.4 24-Aug-18 -13.7 25-Aug-18 -13.6 26-Aug-18 -13.4 27-Aug-18 -13.1 28-Aug-18 -13.7 29-Aug-18 -13.3 30-Aug-18 -13.3 31-Aug-18 -13 01-Sep-18 -13.5 02-Sep-18 -13.1 03-Sep-18 -13.3 04-Sep-18 -12.8 05-Sep-18 -13.2 06-Sep-18 -13.3 07-Sep-18 -13.9 08-Sep-18 -13 09-Sep-18 -13 10-Sep-18 -12.8 11-Sep-18 -13 12-Sep-18 -13 13-Sep-18 -13.3 14-Sep-18 -13.3 15-Sep-18 -13.1 16-Sep-18 -10 17-Sep-18 -14.6 19-Sep-18 -14 20-Sep-18 -13.7

	21-Sep-18 -14.9 22-Sep-18 -14.4 23-Sep-18 -14.4 24-Sep-18 -13.6 25-Sep-18 -14.4 26-Sep-18 -13.3 27-Sep-18 -11.6 28-Sep-18 -10.9 29-Sep-18 -8.5 30-Sep-18 -11.4 01-Oct-18 -11.4 02-Oct-18 -14.1 04-Oct-18 -12.3 05-Oct-18 -13.2 06-Oct-18 -11.5 07-Oct-18 -14.2 08-Oct-18 -14.3 09-Oct-18 -14.5 10-Oct-18 -14.3 4. In an interview at 14:18 hours on 10/10/2018 in the laboratory, the Laboratory Manager stated the laboratory was unaware of the storage requirements for the Siemens Dimension Creatine Kinase (CKI)/Creatine Kinase MB (MBI) calibrators but had a freezer that kept more appropriate temperatures in the laboratory that the calibrators could be moved to. II. Based on surveyor observations, review of Beckman Coulter reagent instructions for storage, laboratory temperature records, and interview with facility personnel, the laboratory failed to store the Beckman Coulter reagents at the required temperature for 35 of 283 days between January 1, 2018 and October 10, 2018. The findings included: 1. At 13:57 hours on 10/10/2018 in the laboratory, the surveyor observed the following Beckman Coulter hematology reagents stored in the laboratory: 3 bottles of Coulter AcT-5-Diff White Blood Cell (WBC) reagent (erythrocyte lysing agent) 3 bottles of Coulter AcT-5-Diff Fix reagent 4 bottles of Coulter AcT-5-Diff Rinse reagent 1 cube of Coulter AcT-5-Diff Diluent - in use on the hematology analyzer All of the reagents listed above required storage temperatures between 18 Celsius and 25 Celsius (64.4 Fahrenheit and 77 Fahrenheit). 2. Based on a review of laboratory temperatures between January 1, 2018 and October 10, 2018, the recorded temperatures were outside of acceptable limits on the following dates: Date Temperature in Fahrenheit 05-Jan-18 63.1 06-Jan-18 63 09-Jan-18 61.8 10-Jan-18 61.2 12-Jan-18 62.1 13-Jan-18 60.1 14-Jan-18 64 16-Jan-18 63 17-Jan-18 58.2 22-Jan-18 64.3 25-Jan-18 64.3 02-Feb-18 62.4 03-Feb-18 62.8 04-Feb-18 63.5 05-Feb-18 64.2 07-Feb-18 63.7 08-Feb-18 63.9 09-Feb-18 63.7 10-Feb-18 63.9 11-Feb-18 61 12-Feb-18 63.6 18-Feb-18 59.8 30-Mar-18 61.4 31-Mar-18 63 07-Apr-18 63.1 15-Apr-18 63 29-Apr-18 63.5 08-May-18 63.5 16-May-18 64.2 17-May-18 63.4 18-May-18 61.2 25-May-18 62.4 25-Jul-18 59.8 01-Aug-18 62.1 04-Aug-18 63.9 3. In an interview at 14:18 hours on 10/10/2018 in the laboratory, the Laboratory Manager stated the laboratory was not aware of the 18 to 25 degree Celsius requirements on the Beckman Coulter hematology reagents and stated "it gets really cold".
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 the laboratory's policies and procedures, the Beckman Coulter AcT-5Diff hematology analyzer verification study, random review of patient records, and interview with facility personnel, the laboratory failed to verify 5 of 5 review analyte reference ranges prior to performing patient testing between May 23, 2017 and October 9, 2018. The findings included: 1. Based on review of the laboratory's procedure "Verification of Performance Specifications" (Date Developed: Dec-12, Date Revised: Dec-12), the policy states the following: "Reference Ranges: The span

of values that you would expect to see in a normal healthy patient population. Reference ranges establish the normal values for the test and reflect the medical decision limits for clinicians. Initially you would use the manufacturer's suggested reference ranges. the lab should monitor the applicability of the reference range and should reflect any variances due to patient population (pediatrics, geriatrics, etc.)" And; "Reference range is established by the manufacturer and can be used initially. But the lab must monitor the normal range and make adjustments as necessary. Compare manufacturer's reference range to the data obtained when testing normal patients. *Collect specimens from 10 to 20 normal patients *Test each specimen once but spread testing over a minimum of three days. *Calculate the mean and SD and determine the two SD range. *Compare this range to the manufacturer's range. If the lab's ranges fall within the manufacturer's range, the reference range is comparable. Perform this check periodically as part of the quality assessment program. In the event that the range obtained are not comparable, the lab will need to establish and appropriate reference range." 2. Based on surveyor observations of the operator's manual stored digitally on the Beckman Coulter AcT-5-Diff at 14:26 hours on 10/09 /2018 in the laboratory, the digitally stored operator's manual did not list the manufacturer's reference ranges. The Laboratory Manager was able to find document "UPDATES TO YOUR MANUALS" (PN 773075AE) on-line. On page 2-1, the Beckman Coulter AcT-5-Diff reference ranges are listed as follows: "Reference Range Studies: A Normal Range Study was conducted to assess the Reference Ranges for the Ac*T 5diff Cap Pierce. Whole blood samples were collected from approximately one hundred and twenty-four normal donors (males and females). The selection of donors complied with the CLSI (former NCCLS), C28-A2 guidelines. These ranges can be used as default values for normal range flags. Your patient population Ranges may be different." Table 2.1 Whole Blood Reference Ranges Overall Parameter: White blood cell (WBC) Units: x1,000/uL (multiply by 1000 per microliter) 95 percent Confidence Low Limit: 3.53 95 percent Confidence High Limit: 9.26 Parameter: Red blood cell (RBC) Units: x1,000,000/uL (multiply by 1,000,000 per microliter) 95 percent Confidence Low Limit: 3.91 95 percent Confidence High Limit: 5.46 Parameter: Hemoglobin Units: grams per deciliter (g /dL) 95 percent Confidence Low Limit: 11.38 95 percent Confidence High Limit: 16.14 Parameter: Hematocrit Units: percent 95 percent Confidence Low Limit: 34.33 95 percent Confidence High Limit: 47.44 Parameter: Platelet count (PLT) Units: x1, 000/uL (multiply by 1000 per microliter) 95 percent Confidence Low Limit: 141 95 percent Confidence High Limit: 375 3. Based on review of the Beckman Coulter AcT 5diff hematology analyzer verification study, the study was prepared by the Beckman Coulter Application Specialist and Accepted by the Laboratory Director on 5/23/2017. On page 22 of the Beckman Coulter "Hematology Method Comparison - Report Interpretation Guide", the document states the following: "Reference Interval (RI) Statistics: When lower and upper limits of the Reference Interval, (LRL and URL) are entered in the study setup for the X method, new Y calculated Reference Intervals are calculated b entering those X values into the regression equation." Based on review of the verification study documentation, there was no evaluation of the manufacturer's reference ranges as described in either the laboratory's procedure "Verification of Performance Specifications" or the manufacturer's prepared study. 4. Based on review of the laboratory's procedure "Hematology Procedure" (Developed: Setp-13, Date Revise: May-14, Date Reviewed: November-16, Approved: Nov 21, 2016) no reference range or normal values are listed in the procedure as required at 42 CFR 493.1251(b)(10) in Appendix C of the CLIA regulations. 5. Based on review of patient records, the reference ranges in use did not match the manufacturer's reference ranges. Eight (8) random patient final reports were reviewed. The reference ranges listed on the final reports of 3 of the 8 specimens are listed below: FIN: C100032074

	Demographic - 79 years old - Male WBC: 5.0- 11.0 RBC: 4.5 - 6.5 Hemoglobin: 13.0 - 18.0 Hematocrit: 42.0-52.0 Platelet (PLT): 130 - 400 FIN: C100032055 Demographic: 80 years old - Female WBC: 5.0- 11.0 RBC: 4.5 - 6.5 Hemoglobin: 13.0 - 16.0 Hematocrit: 42.0-52.0 Platelet (PLT): 130 - 400 FIN: C100032091 Demographic: 15 years old - Female WBC: 5.0- 11.0 RBC: 4.5 - 6.5 Hemoglobin: 13.0 - 16.0 Hematocrit: 42.0-52.0 Platelet (PLT): 130 - 400 6. In an interview at 14:26 hours on 10/09/2018 in the laboratory, the Laboratory Manager (Testing Person 1 on the CMS-209 personnel report) stated the laboratory had adopted reference ranges from another facility and had thought the reference ranges had been verified when the application specialist installed the instrument. When asked how the adopted reference ranges had been established, the Laboratory Manager stated that she did not know how the adopted ranges had been established.
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 laboratory policies and procedures, assay instructions for use, calibration verification records, and interview with facility personnel, the laboratory failed to perform calibration verification procedures at least every 6 months for 3 of 3 analytes over 3 of 3 six month spans between 12/30/2016 and October 10, 2018. The findings included: 1. Control activities routinely used to satisfy the requirement for 493.1256 do not satisfy the calibration verification requirements. EXCEPTIONS: a. Laboratories must perform and document calibration procedures following the manufacturer's test system instructions, using calibration materials provided or specified, and at a frequency that meets or exceeds that recommended by the manufacturer. Where the manufacturer does not provide such instruction, the laboratory may calibrate using 3 or more levels of calibration materials that include a low, mid, and high value at least every 6 months. b. For automated cell counters, the calibration verification requirements are considered met if the laboratory follows the manufacturer's instructions for instrument operation and tests 2 levels of control materials each day of testing provided the control results meet the laboratory's criteria

	for acceptability. This exception does not apply to centrifugal hematology test systems. c. For automated chemistry analyzers, the calibration verification requirements are considered met if the laboratory follows the manufacturer's instructions for instrument operation and routinely tests three (3) levels of control materials (lowest level available, mid-level, and highest level available) more than once each day of testing, the control material results meet the laboratory's criteria for acceptability and the control materials are traceable to National Institute of Standards and Technology (NIST) reference materials. Calibration materials, proficiency testing samples with known results, or control materials with known values may be used to perform calibration verification. For these materials, the laboratory must define acceptable limits for the difference between the measured value obtained, versus the actual concentration of the materials. NOTE: PT samples can only be used after the event cut-off date. 2. Based on review of the Siemens QuikLYTE Integrated Multisensor for the three analytes Sodium (NA), Potassium (K), and Chloride (Cl), (Ref S600, Issue date: 2009-01-29), the document states the following: "Calibration: The Dimension IMT system will routinely perform a one-point calibration with each sample measurement. In addition, the system performs a two-point automatic calibration in duplicate every 2 hours if non analysis is in progress." In an interview at 14:50 hours on 10/10/ 2018 in the laboratory, the Laboratory Manager stated the laboratory performed quality control once each day of patient testing. The analytes Sodium (NA), Potassium (K), and Chloride (Cl), have a two-point calibration and quality control is performed once each day of patient testing; the 3 of 3 analytes do not meet the exceptions to calibration verification requirements listed above. 3. Based on a review of calibration verification records, the last calibration verification procedures were performed on 12/29/2016. Calibration Verification procedures are required at least every 6 months. Six months from 12/29/2016 would have been 6/30 /2017. Six months from 6/30/3017 would have been 12/29/17. Six months from 12/29 /2017 would have been 6/29/2018. There were no other records of calibration verification procedures available for review at the time of the survey. 4. In an interview at 14:54 hours on 10/10/2018 in the laboratory, the Laboratory Manager stated the last calibration verification that had been performed for analytes in routine chemistry had been performed on 12/29/2016.
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: I. Based on review of laboratory policies and procedures, quality control records, and interview with facility personnel, the laboratory failed to monitor the accuracy and precision over time for 4 of 4 lots of quality control materials used between January 11, 2017 and October 10, 2018 for the Opti-CCA blood gas analyzer. The findings

	included: 1. Based on review of the laboratory's procedure "ABG Procedure" (Date Developed: July-13, Approved: Dec-15), under QUALITY CONTROL, the procedure states the following: "Daily quality control requires running three Standard Reference Cassettes (SRC), of different levels, each day of use. Results should fall within limits supplied with the SRC's. Three levels of external wet QC are to be performed each day of patient testing using manufacturer recommended external QC products. On initial use of each lot of cassettes and each month afterward, validation of the lot should be performed using Roche OPTI CHECK wet QC or an equivalent material. This material should provide target values for analytes measured. Quality control material and Proficiency testing material should be aspirated directly form the ampule to help minimize sensitivity to pre-analytic errors." The procedure does not detail how the accuracy and precision of the external or "wet" quality control will be monitored over time. 2. Based on review of quality control records between January 11, 2017 and October 10, 2018, the laboratory has used the following 4 of 4 lots of quality control materials to assess instrument and reagent performance: Lot: 6179 Expiration: April 2018 Lot: 6279 Expiration: April 2018 Lot: 7119 Expiration: August 2019 Lot: 7219 Expiration: August 2019 3. In an interview at 11:09 hours on 10/10/2018 in the laboratory, the Laboratory Manager stated that each lot of control was verified prior to use and assessed for acceptability each day of patient testing. When the surveyor asked if the accuracy and precision of quality control materials were monitored over time, the Laboratory Manager stated "No". II. Based on review of laboratory policies and procedures, quality control records, and interview with facility personnel, the laboratory failed to monitor the accuracy and precision over time for 13 of 13 lots of quality control materials used between January 31, 2017 and October 10, 2018 to monitor the performance of the Cardiac Panel and D-Dimer Panel tested on the Alere Triage analyzer. The findings included: 1. Based on review of the laboratory's procedure "TRIAGE Cardiac Panel Test Procedure" (Date Developed: Aug-13), under QUALITY CONTROL, the procedure states the following: "Two levels of external wet QC should be run upon receipt of each new lot and every day of patient testing for the Triage Cardiac panel as these are mid-complexity tests. External controls are stored in the Chemistry Freezer. Thaw individual vials when needed. for further information regarding the complete quality control of the system, refer to the Operator's Manual for the Triage Meter." The procedure does not detail how the accuracy and precision of the external or "wet" quality control will be monitored over time. 2. Based on review of quality control records between January 31, 2017 and October 10, 2018, the laboratory has used the following 13 of 13 lots of Triage total 5 Control quality control materials to assess instrument and reagent performance: Lot: C3274A - in use 1/31/2017 Expiration: 20171119 Lot: C3278A - in use 1/31/2017 Expiration: 20171007 Lot: C3280A - in use 3/2/17 Expiration: 20171125 Lot: C3298A - in use 4/1/17 Expiration: 20180109 Lot: C3283A - in use 4/1/17 Expiration: 20180115 Lot: C3346A - in use 8/11/2017 Expiration: 20180422 Lot: C3361A - in use 8/11/17 Expiration: 20180428 Lot: C3349A - in use 10/19/17 Expiration 20180622 Lot: C3364A - in use 10/19/17 Expiration 20180621 Lot: C3353A -in use 1/24/18 Expiration: 20180802 Lot: C3368A - in use 1/24/18 Expiration: 20180809 Lot: C3401A - currently in use at time of survey on 10/10/18 Expiration: 20190309 Lot: C3405A - currently in use at time of survey on 10/10/18 Expiration: 20190225 3. In an interview at 11:09 hours on 10/10/2018 in the laboratory, the Laboratory Manager stated that each lot of control was verified prior to use and assessed for acceptability each day of patient testing. When the surveyor asked if the accuracy and precision of quality control materials were monitored over time, the Laboratory Manager stated "No". Deficiencies at 42 CFR 493.1256 Control Procedures were cited on the previous survey conducted on 11/03/2016. This is a repeat deficiency.

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 review of the Bio-Rad Lyphochek Immunoassay Plus Control Levels 1, 2, and 3 and Liquid Assayed Multiqual 1,2,3 instructions for use, laboratory quality control records, and interview with facility personnel, the laboratory failed to establish acceptability criteria for 6 of 6 lots of control material in use between November 20, 2017 and October 10, 2018. The findings included: 1. Based on review of the Bio-Rad Lyphochek Immunoassay Plus Control Levels 1, 2, and 3 and the Liquid Assayed Multiqual 1,2,3 instructions for the use, under "Assignment of Values", the document states: "The mean values and corresponding plus/minus 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analysis and are specific for this lot of product. " And; "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control." 2. Based on review of the laboratory's quality control limits, the laboratory had adopted the plus /minus 3SD ranges of the Bio-Rad controls and had set the limits as plus/minus 2 SD. Examples: Bio-Rad Liquid Assayed Multiqual Level 1 (lot 45781) Analyte: Glucose plus/minus 3SD ranges provided as guides from manufacturer: 55 - 65.4 For this control, the laboratory had the plus/minus 2 SD limits set at 55 - 65.4. Bio-Rad Liquid Assayed Multiqual Level 2 (lot 45782) Analyte: Urea Nitrogen (BUN) plus/minus 3SD ranges provided as guides from manufacturer: 32.2 - 42.8 For this control, the laboratory had the plus/minus 2 SD limits set at 32.2 - 42.8. Bio-Rad Liquid Assayed Multiqual Level 3 (lot 45783) Analyte: Creatinine Kinase (CK) plus/minus 3SD ranges provided as guides from manufacturer: 583 - 674 For this control, the laboratory had the plus/minus 2 SD limits set at 583 - 674 The Bio-Rad Liquid Assayed Multiqual Levels 1, 2 and 3 have been in use to monitor assay performance since 11/20/2017. Bio-Rad Lyphochek Immunoassay Plus Control Levels 1 (lot 40361) Analyte: Vancomycin plus/minus 3SD ranges provided as guides from manufacturer: 4.33 - 7.99 For this control, the laboratory had the plus/minus 2 SD limits set at 4.33 - 7.99. Bio-Rad Lyphochek Immunoassay Plus Control Levels 2 (lot 40362) Analyte: Digoxin plus/minus 3SD ranges provided as guides from manufacturer: 1.71 - 2.38 For this control, the laboratory had the plus/minus 2 SD limits set at 1.71 - 2.38. Bio-Rad Lyphochek Immunoassay Plus Control Levels 3 (lot 40363) Analyte: Acetaminophen plus/minus 3SD ranges provided as guides from manufacturer: 110 - 125 For this control, the laboratory had the plus/minus 2 SD limits set at 110 - 125 3. Based on the laboratory's policy "Laboratory Quality Control Guidelines" (Date Developed: Aug-13, Date Revised: Nov-16, Date Reviewed

	/Approved: Nov-16), on page 3 of 10 under Guideline for Accepting QC Pattern, the policy states the following: "2. 95 percent of values should lie between the plus/minus 2 S ranges and 99 percent between the plus/minus 3S limits. This means that 1 data point in 20 should fall between either the 2S and 3S limits and 1 Data point in 100 will fall outside the 3S limits in a correctly operating system." 3. In general, the plus /minus 2S limits are considered to be warning limits. Values falling between 2S and 3S indicates the analysis should be repeated. The plus/minus 3S limits are rejection limits. When a value falls outside of these limits, the analysis should stop, patient results held, and the test system investigated." Note: When the laboratory sets the manufacturer's provided 3SD guides as plus/minus 2 SD warning limits, the value the laboratory would perceive as being a 3SD rejection limit would actually be 4.5 SD from the mean. Example: Bio-Rad Lyphochek Immunoassay Plus Control Levels 1 (lot 40361) Analyte: Vancomycin plus/minus 3SD ranges provided as guides from manufacturer: 4.33 - 7.99 with a mean of 6.16 The limits of 4.33 - 7.99 are a total 6 standard deviation spread, 3SD above the mean of 6.6 and 3SD below 6.6. In this case 7.99-4.33= 3.66 3.66/6=0.61 With a mean of 6.16 1 SD span would be 5.55 - 6.77 2 SD span would be 4.94- 7.38 3SD span would be the published 4.33 - 7.99 When the 3SD limits are incorrectly mistaken for 2SD warning limits: A published mean of 6.16 1 SD span would be 5.245 - 7.07 2 SD span would be 4.33 - 7.99 3SD span would be the published 3.415 - 8.905 Using the manufacturer's calculated SD = 0.61 from the assay sheet: 8.905- 6.16 = 2.745 (span from the incorrect 3SD upper limit to the published mean) 2.745/.61 = 4.5 When the span between the incorrected upper limit 3SD is divided by the correct 1SD interval of 0.61, the resulting value is 4.5SD from the mean. The laboratory's policy stated that 1 out of every 20 values should statistically lie between 2 SD and 3SD and 1 out of 100 will fall outside of the 3SD rejection limits. With the laboratory's values being incorrectly set, the statistical likelihood of a point falling outside of the 4.5SD limits is 1 in 147,160 events, or once every 403 years for daily quality control events. 4. In an interview at 15:10 hours on 10/10/ 2018 in the laboratory, the Laboratory Manager (listed as Testing Person 1 on the CMS-209 laboratory personnel report) stated that the laboratory had been using the provided plus or minus 3SD ranges in place of what the laboratory had thought was plus or minus 2SD for acceptability criteria and had not established acceptability criteria for the 3 of 3 lots. Key: SD - Standard deviation Deficiencies at 42 CFR 493.1256 Control Procedures (D5469) were cited on the November 10, 2016 inspection. This is a repeat deficiency.
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 review of the laboratory's policies and procedures, hematology analyzer verification records, Bio-Rad control instructions for use, quality control records, surveyor observation, and staff interview, the laboratory failed to follow written policies and procedures to monitor, assess and correct problems in the analytic laboratory systems specified at 493.1251 through 493.1283 for December 2016 through October 10, 2018. The findings included: Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and

	non-technical functions at all location/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and the non-laboratory areas or the facility of which it is a part. When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate. Over time, the laboratory must monitor the corrective action(s) to ensure the action(s) taken have prevented recurrence of the original problem. All pertinent laboratory staff must be involved in the assessment process through discussions or active participation. QA of the Analytic System includes assessing: o Test procedures; o Accurate and reliable test systems, equipment, instruments, reagents, materials, and supplies; o Specimen and reagent storage condition; o Equipment/instrument/test/system maintenance and function checks; o Establishment and verification of method performance specifications; o Calibration and calibration verification; o Control procedures; o Comparison of test results; o Corrective actions; and o Test records. The steps taken by the laboratory to identify and correct problems and prevent their recurrence must be documented. All laboratory policies amended due to its QA activities must also be noted. 1. The laboratory's quality assurance activities failed to detect that the laboratory failed to store the Siemens Dimension CKI/MBI calibrators at the required temperature for 48 of 50 days between August 22, 2018 and October 10, 2018. Refer to D5413-I. 2. The laboratory's quality assurance activities failed to detect that the laboratory failed to store the Beckman Coulter reagents at the required temperature for 35 of 283 days between January 1, 2018 and October 10, 2018. Refer to D5413-II. 3. The laboratory's quality assurance activities failed to detect that the laboratory failed to verify 5 of 5 review analyte reference ranges prior to performing patient testing between May 23, 2017 and October 9, 2018. Refer to D5421. 4. The laboratory's quality assurance activities failed to detect that the laboratory failed to perform calibration verification procedures at least every 6 months for 3 of 3 analytes over 3 of 3 six month spans between 12/30/2016 and October 10, 2018. Refer to D5439. 5. The laboratory's quality assurance activities failed to detect that the laboratory failed to monitor the accuracy and precision over time for 4 of 4 lots of quality control materials used between January 11, 2017 and October 10, 2018 for the Opti-CCA blood gas analyzer. Refer to D5441 - I. Deficiencies at 42 CFR 493.1256 Control Procedures were cited on the previous survey conducted on 11/03/2016. This is a repeat deficiency. 6. The laboratory's quality assurance activities failed to detect that the laboratory failed to monitor the accuracy and precision over time for 13 of 13 lots of quality control materials used between January 31, 2017 and October 10, 2018 to monitor the performance of the Cardiac Panel and D-Dimer Panel tested on the Alere Triage analyzer. Refer to D5441-II. Deficiencies at 42 CFR 493.1256 Control Procedures were cited on the previous survey conducted on 11/03/2016. This is a repeat deficiency. 7. The laboratory's quality assurance activities failed to detect that the laboratory failed to establish acceptability criteria for 6 of 6 lots of control material in use between November 20, 2017 and October 10, 2018. Deficiencies at 42 CFR 493.1256 Control Procedures (D5469) were cited on the November 10, 2016 inspection. This is a repeat deficiency. Refer to D5469.
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 review of laboratory policies and procedures, hematology analyzer verification records, patient records, quality control records, testing personnel competency assessments, and interview with facility personnel, the Technical Consultant failed to provide technical oversight of the laboratory between December 2016 and October 10, 2018. The findings included: 1. Based on a review of the laboratory's policies and procedures, the Beckman Coulter AcT-5Diff hematology analyzer verification study, random review of patient records, and interview with facility personnel, the Technical Consultant failed to ensure the laboratory verified 5 of 5 reviewed analyte reference (normal) ranges prior to performing patient testing between May 23, 2017 and October 9, 2018. Refer to D5421. Refer to D6040. 2. Based on a review of the laboratory's policies and procedures, quality control records, and interview with facility personnel, the Technical Consultant failed to establish a quality control program appropriate for the testing performed and establish the parameters for acceptable levels of analytic performance and ensure that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results between December 2016 and October 10, 2018. Refer to D6042. 3. Based on review laboratory policies, personnel competency assessments, and interview with facility personnel, the Technical Consultant failed to directly observe routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing for 3 of 3 testing personnel in 2017. Refer to D6047. 4. Based on review laboratory policies, personnel competency assessments, and interview with facility personnel, the Technical Consultant failed to directly observe performance of instrument maintenance and function checks for 3 of 3 testing personnel in 2017.Refer to D6050. Deficiencies at 42 CFR 493.1409: Condition - Technical Consultant (Moderate Complexity) were cited on the previous survey conducted on 11/03/2016. This is a repeat deficiency.
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 the laboratory's policies and procedures, the Beckman Coulter AcT-5Diff hematology analyzer verification study, random review of patient records, and interview with facility personnel, the Technical Consultant failed to ensure the laboratory verified 5 of 5 reviewed analyte reference ranges prior to performing patient testing between May 23, 2017 and October 9, 2018. 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 the laboratory's policies and procedures, quality control records, and interview with facility personnel, the Technical Consultant failed to establish a quality control program appropriate for the testing performed and establish the parameters for acceptable levels of analytic performance and ensure that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results between December 2016 and October 10, 2018. The findings included: 1. Based on a review of laboratory policies and procedures, assay instructions for use, calibration verification records, and interview with facility personnel, the Technical Consultant failed to ensure the laboratory performed calibration verification procedures at least every 6 months for 3 of 3 analytes over 3 of 3 six month spans between 12/30/2016 and October 10, 2018. Refer to D5439. 2. Based on review of laboratory policies and procedures, quality control records, and interview with facility personnel, the Technical Consultant failed to ensure the laboratory monitored the accuracy and precision over time for 4 of 4 lots of quality control materials used between January 11, 2017 and October 10, 2018 for the Opti-CCA blood gas analyzer. Refer to D5441 - I. Deficiencies at 42 CFR 493.1256 Control Procedures were cited on the previous survey conducted on 11/03 /2016. This is a repeat deficiency. Refer to D5441-I. 3. Based on review of laboratory policies and procedures, quality control records, and interview with facility personnel, the Technical Consultant failed to ensure the laboratory monitored the accuracy and precision over time for 13 of 13 lots of quality control materials used between January 31, 2017 and October 10, 2018 to monitor the performance of the Cardiac Panel and D-Dimer Panel tested on the Alere Triage analyzer. Refer to D5441-II. Deficiencies at 42 CFR 493.1256 Control Procedures were cited on the previous survey conducted on 11/03/2016. This is a repeat deficiency. Refer to D5441-II. 6. Based on review of the Bio-Rad Lyphochek Immunoassay Plus Control Levels 1, 2, and 3 and Liquid Assayed Multiqual 1,2,3 instructions for use, laboratory quality control records, and interview with facility personnel, the Technical Consultant failed to ensure the laboratory established acceptability criteria for 6 of 6 lots of control material in use between November 20, 2017 and October 10, 2018. Deficiencies at 42 CFR 493.1256 Control Procedures (D5469) were cited on the November 10, 2016 inspection. This is a repeat deficiency. Refer to D5469. Deficiencies at 42 CFR 493.1413 Technical Consultant Responsibilities - were cited on the previous survey conducted on 11/03 /2016. This is a repeat deficiency.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review laboratory policies, personnel competency assessments, and interview with facility personnel, the Technical Consultant failed to directly observe routine patient test performance, including patient preparation, if applicable, specimen

	handling, processing and testing for 3 of 3 testing personnel in 2017. The findings included: 1. Based on a review of the laboratory policy "Technical Supervisor /Consultant", under the section ESSENTIAL FUNCTIONS, the policy states the following: "Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform testing procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to -- i) Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; ii) Monitoring the recording and reporting of test results; iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; iv) Direct observation of performance of instrument maintenance and function checks; v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and vi) Assessment of problem solving skills; and *Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation." 2. Based on review of the competency assessment for Testing Person 21(as listed on the CMS-209 laboratory personnel report), signed by the Technical Consultant on 6/27/2017, each task was marked with the initials of the Laboratory Manager under the column "Self-Assessment". Based on review of the competency assessment for Testing Person 1 (as listed on the CMS-209 laboratory personnel report), signed by the Technical Consultant on September 18, 2018, each task was marked with the initials of the Laboratory Manager under the column "Self-Assessment". Based on review of the competency assessment for Testing Person 2 (as listed on the CMS-209 laboratory personnel report), signed by the Technical Consultant on 6/27/2017, each task was marked with the initials of the Laboratory Manager and the letter "O" under the column "Skill Validated". Based on review of the competency assessment for Testing Person 2 (as listed on the CMS-209 laboratory personnel report), signed by the Technical Consultant on September 18, 2018, each task was marked with the initials of the Laboratory Manager and the letter "O" under the column "Skill Validated". Based on review of the competency assessment for Testing Person 3 (as listed on the CMS-209 laboratory personnel report), signed by the Technical Consultant on 3/29 /2017, each task was marked with the initials of the Laboratory Manager and the letter "O" under the column "Skill Validated". Based on review of the competency assessment for Testing Person 3 (as listed on the CMS-209 laboratory personnel report), signed by the Technical Consultant on September 18, 2018, each task was marked with the initials of the Laboratory Manager and the letter "O" under the column "Skill Validated". 3. In an interview at 16:32 hours on 10/09/2018 in the laboratory, the Laboratory Manager (listed as Testing Person 1 on the CMS-209 laboratory personnel report) stated that Testing Personnel 2 and Testing Personnel 3 would perform a self-assessment initially and then she would observe the individuals perform various tasks. The laboratory manager stated that she would perform the direct observation and the Technical Consultant would sign off that the competency assessments had been completed. When asked if the Technical Consultant directly observe routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing, the Laboratory Manager stated "No".
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

This STANDARD is not met as evidenced by:
Based on review laboratory policies, personnel competency assessments, and interview with facility personnel, the Technical Consultant failed to directly observe performance of instrument maintenance and function checks for 3 of 3 testing personnel in 2017. The findings included: 1. Based on a review of the laboratory policy "Technical Supervisor/Consultant", under the section ESSENTIAL FUNCTIONS, the policy states the following: "Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform testing procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to -- i) Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; ii) Monitoring the recording and reporting of test results; iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; iv) Direct observation of performance of instrument maintenance and function checks; v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and vi) Assessment of problem solving skills; and *Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation." 2. Based on review of the competency assessment for Testing Person 21(as listed on the CMS-209 laboratory personnel report), signed by the Technical Consultant on 6/27/2017, each task was marked with the initials of the Laboratory Manager under the column "Self-Assessment". Based on review of the competency assessment for Testing Person 1 (as listed on the CMS-209 laboratory personnel report), signed by the Technical Consultant on September 18, 2018, each task was marked with the initials of the Laboratory Manager under the column "Self-Assessment". Based on review of the competency assessment for Testing Person 2 (as listed on the CMS-209 laboratory personnel report), signed by the Technical Consultant on 6/27/2017, each task was marked with the initials of the Laboratory Manager and the letter "O" under the column "Skill Validated". Based on review of the competency assessment for Testing Person 2 (as listed on the CMS-209 laboratory personnel report), signed by the Technical Consultant on September 18, 2018, each task was marked with the initials of the Laboratory Manager and the letter "O" under the column "Skill Validated". Based on review of the competency assessment for Testing Person 3 (as listed on the CMS-209 laboratory personnel report), signed by the Technical Consultant on 3/29/2017, each task was marked with the initials of the Laboratory Manager and the letter "O" under the column "Skill Validated". Based on review of the competency assessment for Testing Person 3 (as listed on the CMS-209 laboratory personnel report), signed by the Technical Consultant on September 18, 2018, each task was marked with the initials of the Laboratory Manager and the letter "O" under the column "Skill Validated". 3. In an interview at 16:32 hours on 10/09/2018 in the laboratory, the Laboratory Manager (listed as Testing Person 1 on the CMS-209 laboratory personnel report) stated that

	Testing Personnel 2 and Testing Personnel 3 would perform a self-assessment initially and then she would observe the individuals perform various tasks. The laboratory manager stated that she would perform the direct observation and the Technical Consultant would sign off that the competency assessments had been completed. When asked if the Technical Consultant directly observed performance of instrument maintenance and function checks, the Laboratory Manager stated "No".