Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0470030	08/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Purcell Municipal Hospital	2301 N 9th Ave, Purcell, OK	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The recertification survey was performed on 08/09,10,11,12/2022. The laboratory was found out of compliance with the following CLIA Conditions of Participation: 493.1250; D5400: Analytic Systems 493.1403; D6000: Laboratory Director 493.1409; D6033: Technical Consultant The findings were reviewed with the laboratory manager and technical consultant at the conclusion of the survey.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, quality control package inserts, and interview with the laboratory manager and technical consultant, the laboratory failed to monitor and evaluate the overall quality of analytic systems and correct identified problems for each specialty and subspecialty of testing performed. Findings include: (1) The laboratory failed to follow the manufacturer's instructions for implementing two of four coagulation reagents. Refer to D5411; (2) The laboratory failed to demonstrate the performance specifications for one of two new test methods. Refer to D5421; (3) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures on the Beckman Coulter Access 2 analyzer for five of 12 months. Refer to D5429; (4) The laboratory failed to perform calibration verification every six months for Hemoglobin A1c testing performed on the Bio-Rad DC-10 analyzer. Refer to D5439; (5) The laboratory failed to have control procedures that monitored the accuracy and precision of the testing process;

	and that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for CKMB, Troponin I, PSA, and TSH testing seven of seven months. Refer to D5441; (6) The laboratory failed to perform two levels of quality control materials four of five days of patient Troponin I and CKMB testing reviewed and two of 21 days of patient Hemoglobin A1c testing reviewed. Refer to D5447; (7) The laboratory failed to perform a negative and positive control material 32 of 34 days of patient urine drug screen testing and 34 of 35 days of qualitative serum pregnancy testing. Refer to D5449; (8) The laboratory failed to follow the manufacturer's specifications for Bio-Rad Liquichek Diabetes control materials for two of two lot numbers. Refer to D5479; (9) The laboratory failed to perform one sample of control material each 8 hours of patient blood gas testing using a combination of control materials that include both low and high values on each day of testing for 13 of 18 patients reviewed. Refer to D5537; (10) The laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different methodologies for two of two test methods. Refer to D5775; (11) The laboratory failed to have an ongoing mechanism for performing quality assessment. Refer to D5791.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager and technical consultant, the laboratory failed to follow the manufacturer's instructions for implementing two of four coagulation reagents. Findings include: (1) On 08/09/2022 at 10:00 am, the laboratory manager stated the ACL TOP analyzer was used to perform patient PT/INR (Prothrombin Time /International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing (the INR was calculated using the PT reference interval mean); (2) On 08/11/2022 at 10:40 am, the laboratory manager stated the reagents were put into use as follows: (a) PT Reagent - HemosIL RecombiPlastIN 2G, lot #N1117938 was put into use on 03/22 /2022; (b) PTT Reagent - HemosIL SynthasIL, lot #N0129380 was put into use on 06 /22/2022. (3) A review of the manufacturer's instructions contained in the "Hemostasis Performance Verification Manual" for implementing new reagents, revealed the following: (a) Under the section titled, "Establishing a Normal Reference Interval" stated for a 20- donor study: (i) "Donors should be equally divided between male/female"; (ii) "Determine the mean, standard deviation (SD) and range once the data has been collected.....For non-Gaussian distributions, such as PT, a geometric mean is recommended". (b) Under the section titled, "Comparison Study" stated: (i) "Normal and Abnormal samples are tested. The new methodology or reagents is assessed against the comparative (usually the current) methodology or reagents"; (ii) "At least 50% of the samples should be outside of the laboratory normal reference interval, if possible"; (iii) "At least 40 specimens should be analyzed" (4) A review of the implementation records for the reagent lot changes revealed the following: (a) HemoSIL RecombiPlastIN 2G (i) Normal Reference Interval (aa) The laboratory had used 18 donors instead of 20, which included eight males and ten females; (bb) The normal patient mean that had been calculated was not the geometric mean. (ii)

	Comparison Study (aa) The laboratory had used 18 normal and two abnormal samples, instead of 20 normal and 20 abnormal specimens. (b) HemoSIL SynthasIL (i) Comparison Study (aa) The laboratory had used 20 normal samples and did not include 20 abnormal samples. (5) The records were reviewed with the laboratory manager and technical consultant. Both stated on 08/11/2022 at 11:15 am, the manufacturer's instructions had not been followed for the reagent lot changes; (6) The following were examples of patient testing: (a) PT/INR Testing (i) Patient #656697875 - Testing performed on 04/25/2022 (ii) Patient #657640693 - Testing performed on 05/17/2022 (iv) Patient #657777513 - Testing performed on 05/20/2022 (v) Patient #658798409 - Testing performed on 06/14/2022 (vi) Patient #659073939 - Testing performed on 06/23/2022 (vii) Patient #659427482 - Testing performed on 06 /29/2022 (viii) Patient #660529846 - Testing performed on 07/26/2022 (ix) Patient #660830447 - Testing performed on 08/02/2022 (b) PTT Testing (i) Patient #659256087 - Testing performed on 06/25/2022 (ii) Patient #659439841 - Testing performed on 06/29/2022 (iii) Patient #660852439 - Testing performed on 08/02/2022
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 and technical consultant, the laboratory failed to demonstrate the performance specifications for one of two new test methods. Findings include: (1) On 08/09/2022 at 03:26 pm, the technical consultant stated the test stated the Fisher Health SureVue Serum hCG STAT test kit was put into use to perform patient serum qualitative pregnancy testing on 07/21/2021; (2) A review of records for the test kit revealed no evidence the performance specifications (accuracy, precision, reportable range, and verification of reference range, as applicable for the test system) had been demonstrated; (3) Interview with the technical consultant on 04/09/2022 at 03:26 pm confirmed the performance specifications, as applicable had not been demonstrated prior to putting the test kit into use for patient testing; (4) Refer to D5449 for examples of patient testing performed.
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 and technical consultant, the laboratory failed to follow the

	manufacturer's instructions for performing maintenance procedures on the Beckman Coulter Access 2 analyzer for five of 12 months. Findings include: (1) On 08/09/2022 at 10:00 am, the laboratory manager stated CKMB, Troponin I, HCG (Human Chorionic Gonadotropin), TSH (Thyroid Stimulating Hormone), Free T4 (Thyroxine), LH (Luteinizing Hormone), Testosterone, Transferrin, Vitamin B12, and Vitamin D testing were performed on the Beckman Coulter Access 2 analyzer; (2) On 08/12 /2022, a review of the manufacturer's maintenance requirements, as stated on the manufacturer's maintenance log required the following: (a) Daily (i) Check Zone Temperature (ii) Check System Supplies (iii) Check Liquid Waste Container (iv) System Backup Successful? (v) Inspect Fluidic Module (vi) Clean Probe Exteriors (vii) Prime Substrate (iii) Run Daily Clean System (b) Weekly (i) Clean Instrument Exterior (ii) Check Waste Filter Bottle (iii) Inspect/Clean Primary Probe (iv) Replace /Clean Aspirate Probes (v) Run System Check (3) A review of maintenance records from August 2021 through July 2022 revealed maintenance had not been documented as performed as follows: (a) Daily (i) Check Zone Temperature, Check System Supplies, Check Liquid Waste Container, System Backup Successful?, Inspect Fluidic Module, Clean Probe Exteriors, Prime Substrate, and Run Daily Clean System had not been documented as performed between 09/19/21 and 09/21/2021; and between 09/23 /2021 and 09/26/2021; (ii) Inspect Fluidic Module, Clean Probe Exteriors, Prime Substrate, and Run Daily Clean System had not been documented as performed between 05/04/2022 and 05/07/2022; and between 05/11/2022 and 05/14/2022; (iii) Clean Probe Exteriors and Prime Substrate had not been documented as performed between 05/22/2022 and 05/24/2022; (iv) Inspect Fluidic Module, Clean Probe Exteriors, Prime Substrate, and Run Daily Clean System had not been documented as performed between 07/24/2022 and 07/30/2022. (b) Weekly (i) Replace/Clean Aspirate Probes had not been documented as performed between 08/06/2021 and 08 /27/2021; (ii) Clean Instrument Exterior, Check Waste Filter Bottle, Inspect/Clean Primary Probe, Replace/Clean Aspirate Probes, and Run System Check had not been documented as performed between 08/27/2021 and 09/22/2021. (4) The records were reviewed with the laboratory manager and technical consultant. Both stated on 08/12 /2022 at 10:10 am, the maintenance had not been documented as performed as shown above.
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 and technical consultant, the laboratory failed to perform calibration verification every six months for Hemoglobin A1c testing performed on the Bio-Rad DC-10 analyzer. Findings include: (1) On 08/09/2022 at 09:50 am, the laboratory manager stated Hemoglobin A1c testing was performed on the Bio-Rad DC-10 analyzer; (2) On 08/10/2022, a review of calibration records revealed the routine calibrations were performed using two calibrators, therefore calibration verification procedures, using at least three levels of calibration materials were required; (3) A review of records from January 2021 through the current date revealed calibration verification had not been performed prior to 08/07/2022; (4) The records were reviewed with the laboratory manager and technical consultant. Both stated on 08/10/2022 at 03:40 pm, calibration verification had not been performed every six months; (5) The following were examples of patient testing performed (patient number represents sample number): (a) Patient #639285136 - Testing performed on 03/05/2021 (b) Patient #639460455 - Testing performed on 03 /10/2021 (c) Patient #64096405 - Testing performed on 04/05/2021 (d) Patient #646560174 - Testing performed on 08/30/2021 (e) Patient #647864207 - Testing performed on 09/29/2021 (f) Patient #648925169 - Testing performed on 10/23/2021 (g) Patient #650002987 - Testing performed on 11/17/2021 (h) Patient #650760075 - Testing performed on 12/06/2021 (i) Patient #653863211 - Testing performed on 02 /16/2022 (k) Patient #654313355 - Testing performed on 02/28/2022 (l) Patient #654544753 - Testing performed on 03/04/2022 (m) Patient #655258373 - Testing performed on 03/22/2022 (n) Patient #655700995 - Testing performed on 04/01/2022 (o) Patient #656703054 - Testing performed on 04/25/2022 (p) Patient #657041608 - Testing performed on 05/03/2022 (q) Patient #657671762 - Testing performed on 05 /18/2022 (r) Patient #658848615 - Testing performed on 06/15/2022 (s) Patient #659215788 - Testing performed on 06/24/2022 (t) Patient #659650595 - Testing performed on 07/05/2022 (u) Patient #660241951 - Testing performed on 07/19/2022 (v) Patient #660273537 - Testing performed on 07/20/2022
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, quality control package inserts, and interview with the laboratory manager and technical consultant, the laboratory failed to have control procedures that monitored the accuracy and precision of the testing process; and that

would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for PTT testing for one of one month; and CKMB, Troponin I, PSA, and TSH testing for seven of seven months. Findings include: ACL TOP ANALYZER (1) On 08/09/2022 at 10:00 am, the laboratory manager stated the ACL TOP analyzer was used to perform patient PTT (Partial Thromboplastin Time) testing; (2) On 08/11/2022 at 10:40 am, the laboratory manager stated the following two levels of control materials were performed each eight hours of patient testing and were put into use on 06/22/2022: (a) HemosIL Normal Control 1, lot #N0129618 and HemosIL Abnormal Control 3, lot #N0129621. (3) A review of QC (Quality Control) records for patient testing performed from 07/01 /2022 through 07/31/2022 revealed the following for one of two levels of QC (HemosIL Abnormal Control 3): (a) A two SD (Standard Deviation) range of 53.89-56.98 had been established by the laboratory when the lot number had been put into use. A range of 50.2-67.8 had been used to evaluate QC results, which was beyond the established range. (4) The records were reviewed with the technical consultant, who stated on 08/11/2022 at 01:54 pm, the laboratory had used a range wider than the established range to evaluate QC results as shown above; (5) Refer to D5411 for examples of patient testing performed. BECKMAN COULTER ACCESS 2 ANALYZER (1) On 08/09/2022 at 10:05 am, the laboratory manager stated the Beckman Coulter Access 2 analyzer was used to perform CKMB (Creatine Kinase Isoenzyme), Troponin I, PSA (Prostate Specific Antigen), and TSH (Thyroid Stimulating Hormone) testing; (2) On 08/12/2022 at 10:30 am, the laboratory manager stated two levels of QC materials were performed each day of CKMB and Troponin I patient testing and three levels of QC materials were performed each day of PSA and TSH patient testing. The laboratory established means and two SD ranges were established for each analyte prior to putting new lot numbers of QC materials into use. The following control materials were currently in use: (a) CKMB and Troponin I testing - Bio-Rad Liquichek Cardiac Markers Plus controls; Level one lot #87831 and Level three lot #87833; (b) PSA and TSH - Bio-Rad Liquichek Immunoassays controls; Level one lot #85271, Level two lot #85272, and Level three lot #85273. (3) A review of QC records (Levey-Jennings graphs and cumulative calculated data; and QC package inserts) from January through July 2022 revealed the following: (a) CKMB and Troponin I (i) The Levey-Jennings graphs reflected the lot numbers in use during the review period as level one lot #29891 and level three lot #29893 (which were not the correct lot numbers); (ii) There was no documentation to show the establishment of the QC ranges, therefore the package insert ranges were used as a guide for the review (note: the package insert ranges were to be used by the laboratory as a guide while establishing QC ranges). The following were identified for two of two QC materials for CKMB and two of two QC materials for Troponin I: (aa) CKMB level one - The laboratory was using a range of 0.60-5.20 which was wider than the package insert guideline range of 1.81-3.16; (bb) CKMB level two - The laboratory was using a range of 3.0-20.20 which was wider than the package insert guideline range of 11.2-15.7; (cc) Troponin I level one - The laboratory was using a range of 0.014-0.394 which was wider than the package insert guideline range of 0.113-0.312; (dd) Troponin I level two - The laboratory was using a range of 0.410-1.73 which was wider than the package insert guideline range of 0.798-1.53. (b) PSA and TSH (i) The Levey-Jennings graphs reflected the lot numbers in use during the review period as level one lot #85261, level two lot #85262, and level three lot #29893 (which were not the correct lot numbers); (ii) There was no documentation to show the establishment of the QC ranges, therefore the package insert ranges were used as a guide for the review. The following were identified for three of three QC materials for PSA and two of three QC materials for TSH: (aa) PSA level one - Beginning 07/01/2022, the laboratory was using a range of -15.8-16.4 which was

wider than the package insert guideline range of 0.325-.502; (bb) PSA level two - Beginning 07/01/2022, the laboratory was using a range of 2.77-5.33 which was wider than the package insert guideline range of 3.17-4.60; (cc) PSA level three - The laboratory was using a range of 14-31.3 which was wider than the package insert guideline range of 22-31.6; (dd) TSH level one - Beginning 07/01/2022, the laboratory was using a range of -0.12-1.474 which was wider than the package insert guideline range of 0.535-0.762; (ee) TSH level two - Beginning 07/01/2022, the laboratory was using a range of 3.58-7.26 which was wider than the package insert guideline range of 4.17-6.07. (4) The records were reviewed with the laboratory manager and technical consultant. Both stated the following on 08/12/2022 at 12:25 pm: (a) CKMB and Troponin I (i) The laboratory had not updated the computer with the new QC lot numbers when the Bio-Rad Liquichek Cardiac Markers Plus level one lot #87831 and level three lot #87833 had been put into use. The exact date the new lot numbers were put into use could not be determined, but they were in use during the review period; (ii) It could not be determined how ranges had been derived that were wider than the package insert guideline ranges for each level of control material. (b) PSA and TSH (i) The laboratory had not updated the computer with the new QC lot numbers when the Bio-Rad Liquichek Immunoassay level one lot #85261, level two lot #85262, and level three lot #29893 had been put into use. The exact date the new lot numbers were put into use could not be determined, but they were in use during the review period; (ii) It could not be determined how ranges had been derived that were wider than the package insert guideline ranges for each level of control material. (5) Examples of patient testing performed during this timeframe (patient number represents hospital account number): (a) CKMB and Troponin I (i) Patient #90722005026 - Testing performed on 01/05/2022 (ii) Patient #907220160117 - Testing performed on 01/16/2022 (iii) Patient #907220200153 - Testing performed on 01/20/2022 (iv) Patient #907220390149 - Testing performed on 02/08/2022 (v) Patient #907220520158 - Testing performed on 02/21/2022 (vi) Patient #907220820112 - Testing performed on 03/23/2022 (vii) Patient #907220980079 - Testing performed on 04/08/2022 (viii) Patient #907221240099 - Testing performed on 05/04/2022 (ix) Patient #907221360064 - Testing performed on 05/16/2022 (x) Patient #907221540046 - Testing performed on 06/03/2022 (xi) Patient #90722167005 - Testing performed on 06/16/2022 (xii) Patient #907221710098 - Testing performed on 06/20/2022 (xiii) Patient #907221830002 - Testing performed on 07/02/2022 (xiv) Patient #907222020023 - Testing performed on 07/21/2022 (b) PSA (i) Patient #907220100165 - Testing performed on 01/10/2022 (ii) Patient #907220590169 - Testing performed on 02/28/2022 (iii) Patient #907220680096 - Testing performed on 03/09/2022 (iv) Patient #907220770093 - Testing performed on 03/18/2022 (v) Patient #907221010112 - Testing performed on 04/11/2022 (vi) Patient #90722110104 - Testing performed on 04/21/2022 (vii) Patient #907221450072 - Testing performed on 05/25/2022 (viii) Patient #907221730010 - Testing performed on 06/22/2022 (ix) Patient #907221870048 - Testing performed on 07/07/2022 (x) Patient #9072221920104 - Testing performed on 07/13/2022 (xi) Patient #907222060075 - Testing performed on 07/25/2022 (c) TSH (i) Patient #907220120003 - Testing performed on 01/12/2022 (ii) Patient #907220470135 - Testing performed on 02/16/2022 (iii) Patient #907220610139 - Testing performed on 03/02/2022 (iv) Patient #907220890155 - Testing performed on 03/30/2022 (v) Patient #907221040122 - Testing performed on 04/14/2022 (vi) Patient #907221110099 - Testing performed on 04/21/2022 (vii) Patient #907221220132 - Testing performed on 05/02/2022 (viii) Patient #907221220164 - Testing performed on 05/03/2022 (ix) Patient #907221500008 - Testing performed on 05/30/2022 (x) Patient #907221570049 - Testing performed on 05/06/2022 (xi) Patient #907221680088 - Testing performed on 06/17/2022 (xii) Patient #907221870069 -

	Testing performed on 07/06/2022 (xiii) Patient #907221970001 - Testing performed on 07/16/2022
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant, the laboratory failed to perform two levels of quality control materials four of five days of patient Troponin I and CKMB testing reviewed and two of 21 days of patient Hemoglobin A1c testing reviewed. Findings include: TROPONIN I AND CKMB (1) On 08/09/2022 at 09:45 am, the laboratory manager stated patient Troponin I and CKMB testing were performed using the BioSite Triage Meter Pro as the back-up method to the Beckman Coulter Access 2 analyzer; (2) On 08/09/2022 at 03:00 pm, the technical consultant stated an IQCP (Individualized Quality Control Program) had not been developed for the test system; (3) A review of QC (Quality Control) and patient testing records for testing performed from January 2022 through April 2022 revealed two levels of QC materials had not been performed each day of patient testing for four of five days reviewed; (4) The records were reviewed with the laboratory manager and technical consultant. Both stated on 08/09/2022 at 03:23 pm, two levels of QC materials had not been performed each day of patient testing; (5) The following were the days of patient testing reviewed when two levels of QC materials had not been tested (patient number represents sample number): (a) Patient #653104722 - Testing performed on 01/28/2022 (b) Patient #653122536 - Testing performed on 01/29/2022 (c) Patient #653133043 - Testing performed on 01/30/2022 (d) Patient #653168609 - Testing performed on 01/31/2022 (e) Patient #656862809 - Testing performed on 04/28/2022 HEMOGLOBIN A1C (1) On 08/09/2022 at 09:47 am, the laboratory manager stated patient Hemoglobin A1c testing was performed using the Bio-Rad D 10 analyzer; (2) A review of QC and patient testing records for testing performed in July 2022 revealed that two levels of QC materials had not been performed each day of patient testing for two of 21 days reviewed; (3) The records were reviewed with the laboratory manager and technical consultant. Both stated on 08 /09/2022 at 03:20 pm, two levels of QC materials had not been performed each day of patient testing; (4) The following were the days of patient testing reviewed when two levels of QC materials had not been tested (patient number represents sample number): (a) Patient #660241951 - Testing performed on 07/19/2022 (b) Patient #660273537 - Testing performed on 07/20/2022
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory manager and technical consultant, the laboratory failed to perform a negative and positive control material 32 of 34 days of patient urine drug screen testing and 34 of 35 days of qualitative serum pregnancy testing. Findings include: URINE DRUG SCREEN (1) On 08/09/2022 at 09:40 am, the laboratory manager stated patient urine drug screen testing was performed using the Bio-Rad TOX/See urine drug screen test kit; (2) On 08/09/2022 at 02:45, the technical consultant stated the test kit was put into use for patient testing on 08/02/2021 and an IQCP (Individualized Quality Control Program) had not been developed for the test system; (3) A review of QC (Quality Control) and patient testing records for testing performed in August 2021, March 2022, and July 2022 revealed negative and positive QC materials had not been performed each day of patient testing for 32 of 34 days; (4) The records were reviewed with the laboratory manager and technical consultant. Both stated on 08/09/2022 at 03:05 pm, negative and positive QC materials had not been performed each day of patient testing; (5) The following were the days of patient testing reviewed when negative and positive QC materials had not been performed (patient number represents sample number or medical record number): (a) Patient #645321489 - Testing performed on 08/02/2021 (b) Patient #645481117 - Testing performed on 08/05/2021 (c) Patient #645529669 - Testing performed on 08/06/2021 (d) Patient #645943298 - Testing performed on 08 /11/2021 (e) Patient #645808996- Testing performed on 08/12/2021 (f) Patient #6458466112 - Testing performed on 08/13/2021 (g) Patient #645876929 - Testing performed on 08/14/2021 (h) Patient #645958037 - Testing performed on 08/16/2021 (i) Patient #646028620 - Testing performed on 08/18/2021 (j) Patient #646110675 - Testing performed on 08/19/2021 (k) Patient #646149920 - Testing performed on 08 /20/2021 (l) Patient #646270257 - Testing performed on 08/24/2021 (m) Patient #646318808 - Testing performed on 08/25/2021 (n) Patient #655261322 - Testing performed on 03/01/2022 (o) Patient #231564 - Testing performed on 03/02/2022 (p) Patient #8188 - Testing performed on 03/07/2022 (q) Patient #236043 - Testing performed on 03/10/2022 (r) Patient #227030 - Testing performed on 03/15/2022 (s) Patient #233377 - Testing performed on 03/21/2022 (t) Patient #218465- Testing performed on 03/22/2022 (u) Patient #5517 - Testing performed on 03/25/2022 (v) Patient #52675 - Testing performed on 03/26/2022 (w) Patient #234056 - Testing performed on 03/30/2022 (x) Patient #90548 - Testing performed on 07/01/2022 (y) Patient #237102 - Testing performed on 07/05/2022 (z) Patient #29257 - Testing performed on 07/08/2022 (aa) Patient #59181 - Testing performed on 07/10/2022 (bb) Patient #237168 - Testing performed on 07/14/2022 (cc) Patient #49978 - Testing performed on 07/18/2022 (dd) Patient #2588 - Testing performed on 07/22/2022 (ee) Patient #237269 - Testing performed on 07/23/2022 (ff) Patient #42447 - Testing performed on 07/30/2022 QUALITATIVE SERUM PREGNANCY (1) On 08/09 /2022 at 09:45 am, the laboratory manager stated Fisher Health SureVue Serum hCG STAT test kit to perform patient qualitative pregnancy testing; (2) On 08/09/2022 at 03:26 pm, the technical consultant stated the test kit was put into use for patient testing on 07/21/2021 and an IQCP (Individualized Quality Control Program) had not been developed for the test system; (3) A review of QC (Quality Control) and patient testing records for testing performed from 01/21/2022 through 08/03/2022 revealed negative and positive QC materials had not been performed each day of patient testing for 34 of 35 days of testing; (4) The records were reviewed with the laboratory manager and technical consultant. Both stated on 08/09/2022 at 03:43 pm, negative and positive QC materials had not been performed each day of patient testing; (5) The following were the days of patient testing reviewed when negative and positive QC

	materials had not been performed (numbers represent specimen number or medical record number): (a) Patient #652772580 - Testing performed on 01/21/2022 (b) Patient #652819965 - Testing performed on 01/22/2022 (c) Patient #652483242 - Testing performed on 01/23/2022 (d) Patient #653083290 - Testing performed on 01 /28/2022 (e) Patient #654041853 - Testing performed on 02/21/2022 (f) Patient #654412230 - Testing performed on 03/02/2022 (g) Patient #32484 - Testing performed on 03/07/2022 (h) Patient #228276 - Testing performed on 03/08/2022 (i) Patient #24991 - Testing performed on 03/10/2022 (j) Patient #211075 - Testing performed on 03/11/2022 (k) Patient #47713 - Testing performed on 03/15/2022 (l) Patient #29035 - Testing performed on 03/18/2022 (m) Patient #43941 - Testing performed on 03/25/2022 (n) Patient #236290 - Testing performed on 04/04/2022 (o) Patient #229722 - Testing performed on 04/07/2022 (p) Patient #236192 - Testing performed on 04/14/2022 (q) Patient #66330 - Testing performed on 04/20/2022 (r) Patient #203359 - Testing performed on 04/21/2022 (s) Patient #236465 - Testing performed on 04/22/2022 (t) Patient #326529 - Testing performed on 04/25/2022 (u) Patient #58823 - Testing performed on 04/27/2022 (v) Patient #73483 - Testing performed on 04/28/2022 (w) Patient #215914 - Testing performed on 05/03/2022 (x) Patient #221128 - Testing performed on 05/08/2022 (y) Patient #220575 - Testing performed on 05/17/2022 (z) Patient #29426 - Testing performed on 06/03/2022 (aa) Patient #168152 - Testing performed on 06/06/2022 (bb) Patient #35529 - Testing performed on 06/09/2022 (cc) Patient #237145- Testing performed on 07/11/2022 (dd) Patient #237194 - Testing performed on 07/18/2022 (ee) Patient #50759 - Testing performed on 07/21/2022 (ff) Patient #15911 - Testing performed on 07/26/2022 (gg) Patient #203555 - Testing performed on 07/28/2022 (hh) Patient # 214353 - Testing performed on 08/03/2022
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager and technical consultant, the laboratory failed to follow the manufacturer's specifications for Bio-Rad Liquichek Diabetes control materials for two of two lot numbers. Findings include: (1) On 08/09/2022 at 09:50 am, the laboratory manager stated: (a) Hemoglobin A1c testing was performed on the Bio-Rad DC-10 analyzer; (b) Two levels of Bio-Rad Liquichek Diabetes control materials were performed each day of patient testing. (2) On 08/10/2022, a review of the manufacturer's instructions (package insert) for the control materials stated, "The mean values and the corresponding +/-3SD ranges in the Assignment of Values Data Charts were derived from replicate analyses and are 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"; (3) A review of QC (Quality Control) records for two lot numbers of control materials revealed the following: (a) Level one lot #55781 and level three lot #55783 were put into use on 02/16/2022 and were

	currently in use; (b) The laboratory had not established their own acceptable ranges and were using the manufacturer's guideline ranges as follows: (i) Level One - 4.15-6.35 (ii) Level Three - 11.8-16.1 (4) The records were reviewed with the laboratory manager and technical consultant. Both stated on 08/10/2022 at 03:34 pm, the laboratory had not followed the manufacturer's instructions for the control materials; (5) The following were examples of patient Hemoglobin A1c testing performed (number represents specimen number): (a) Patient #653863211 - Testing performed on 02/16/2022 (b) Patient #654313355 - Testing performed on 02/28/2022 (c) Patient #654544753 - Testing performed on 03/04/2022 (d) Patient #655258373 - Testing performed on 03/22/2022 (e) Patient #655700995 - Testing performed on 04/01/2022 (f) Patient #656703054 - Testing performed on 04/25/2022 (g) Patient #657041608 - Testing performed on 05/03/2022 (h) Patient #657671762 - Testing performed on 05 /18/2022 (i) Patient #658848615 - Testing performed on 06/15/2022 (j) Patient #659215788 - Testing performed on 06/24/2022 (k) Patient #659650595 - Testing performed on 07/05/2022 (l) Patient #660241951 - Testing performed on 07/19/2022 (m) Patient #660273537 - Testing performed on 07/20/2022
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant, the laboratory failed to perform one sample of control material each 8 hours of patient blood gas testing using a combination of control materials that include both low and high values on each day of testing for 13 of 18 patients reviewed. Findings include: (1) On 08/10/2022 at 10:30 am, the laboratory manager stated the following: (a) Blood gas testing (pH, pCO2, pO2) was performed on the EPOC analyzer; (b) One level of quality control (QC) material was tested each eight hours of patient testing. (2) A review of QC and patient records for testing performed in January 2022, March 2022, and July 2022 revealed that the performance of QC materials did not include both low and high values on each day of testing for 13 of 18 patients reviewed (patient number represents sample number): (a) Patient #652317944 had been tested on 01/11/2022 at 03:09 pm. Level one QC had not been performed and level three QC had been performed at 01:48 pm; (b) Patient #652488927 had been tested on 01/15/2022 at 07:54 pm. Level one QC had been performed at 02:14 am and level three QC had not been performed; (c) Patient #652693798 had been tested on 01 /19/2022 at 08:02 pm. Level one QC had not been performed and level three QC had been performed at 07:44 pm; (d) Patient #652953001 had been tested on 01/25 2022 09:54 pm. Level one QC had been performed at 09:45 pm and level three QC had not been performed; (e) Patient #654412231 had been tested on 03/02/2022 at 06:58 am. Level one QC had not been performed and level three QC had been performed at 06: 53 am; (f) Patient #654735911 had been tested on 03/09/2022 at 01:19 pm. Level one QC had not been performed and level three QC had been performed at 12:58 pm; (g) Patient #654893830 had been tested on 03/13/2022 at 07:56 pm. Level one QC had not been performed and level three QC had been performed at 07:50 pm (h) Patient #655269942 had been tested on 03/22/2022 at 11:45 am. Level one QC had been performed at 11:31 am and level three QC had not been performed; (i) Patient

	#659542985 had been tested on 07/01/2022 at 06:58 pm. Level one and level three QC had not been performed; (j) Patient #659614653 had been tested on 07/04/2022 at 10:54 pm. Level one QC had not been performed and level three QC had been performed at 10:00 pm; (k) Patient #659744291 had been tested on 07/07/2022 at 12: 48 pm. Level one QC had not been performed and level three QC had been performed at 12:43 pm; (l) Patient #660307649 had been tested on 07/20/2022 at 06:01 pm. Level one QC had not been performed and level three QC had been performed at 05: 56 pm; (m) Patient #660652749 had been tested on 07/28/2022 at 06:15 pm. Level one QC had not been performed and level three QC had been performed at 06:09 pm. (3) The records were reviewed with the technical consultant who stated on 08/10/2022 at 12:23 pm, QC testing had not been performed each eight hours to include both low and high values on each day of patient testing.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different methodologies for two of two test methods. Findings include: (1) On 08/09/2022 at 09:40 am, the laboratory manager stated the Beckman Coulter Access 2 analyzer was used as the primary method of performing CKMB and Troponin I testing and the Alere Triage Meter Pro was used as the back-up method; (2) A review of records for testing performed on both test systems from 07/2021 through 07/2022 revealed no evidence the relationship between testing performed on the two test methods had been evaluated at least twice annually; (3) The findings were reviewed with the laboratory manager and technical consultant. Both stated on 08/09/2022 at 03:00 pm, the relationship between the testing performed on the two test methods had not been evaluated twice annually.
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, quality control package inserts, and interview with the laboratory manager and technical consultant, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to follow

	the manufacturer's instructions for implementing two of four coagulation reagents. Refer to D5411; (b) The laboratory failed to demonstrate the performance specifications for one of two new test methods. Refer to D5421; (c) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures on the Beckman Coulter Access 2 analyzer for five of 12 months. Refer to D5429; (d) The laboratory failed to perform calibration verification every six months for Hemoglobin A1c testing performed on the Bio-Rad DC-10 analyzer. Refer to D5439; (e) The laboratory failed to have control procedures that monitored the accuracy and precision of the testing process; and that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for CKMB, Troponin I, PSA, and TSH testing seven of seven months. Refer to D5441; (f) The laboratory failed to perform two levels of quality control materials four of five days of patient Troponin I and CKMB testing reviewed and two of 21 days of patient Hemoglobin A1c testing reviewed. Refer to D5447; (g) The laboratory failed to perform a negative and positive control material 38 of 40 days of patient urine drug screen testing and 36 of 37 days of qualitative serum pregnancy testing. Refer to D5449; (h) The laboratory failed to follow the manufacturer's specifications for Bio-Rad Liquichek Diabetes control materials for two of two lot numbers. Refer to D5479; (i) The laboratory failed to perform one sample of control material each 8 hours of patient blood gas testing using a combination of control materials that include both low and high values on each day of testing for 13 of 18 patients reviewed. Refer to D5537; (j) The laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different methodologies for two of two test methods. Refer to D5775.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, quality control package inserts, and interview with the laboratory manager and technical consultant, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to ensure the individual who performed the duties and responsibilities of the laboratory director, met the qualifications. Refer to D6003; (2) The laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Refer to D6013; (3) The laboratory director failed to ensure test methods were performed as required for accurate and reliable results. Refer to D6014; (4) The laboratory director failed to ensure proficiency testing attestations, stating samples were tested as required under Subpart H, were signed by an individual meeting the regulatory qualifications for three of six attestation statements. Refer to D6016; (5) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (6) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021.
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general

	laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications. This STANDARD is not met as evidenced by: Based on a review of records and interview with the the laboratory manager and technical consultant, the laboratory director failed to ensure the individual who performed the duties and responsibilities of the laboratory director, met the qualifications for three of six attestation statements. Findings include: (1) On 08/09 /2022, a review of proficiency testing records for 2021 and 2022 revealed that three of six attestations statements had been signed by the hospital medical director. There was no documentation to prove the individual met the regulatory qualifications of a laboratory director. Refer to D6016.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance

	characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant, the laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the performance specifications had been demonstrated for one of two new test methods. Refer to D5421.
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 and technical consultant, the laboratory director failed to ensure test methods were performed as required for accurate and reliable results. Findings include: (1) The laboratory director failed to ensure the laboratory followed the manufacturer's instructions for implementing two of four coagulation reagents. Refer to D5411; (2) The laboratory director failed to ensure the laboratory followed the manufacturer's instructions for performing maintenance procedures on the Beckman Coulter Access 2 analyzer for five of 12 months. Refer to D5429.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the the laboratory manager and technical consultant, the laboratory director failed to ensure proficiency testing attestations, stating samples were tested as required under Subpart H, were signed by an individual meeting the regulatory qualifications for three of six attestation statements. Findings include: (1) On 08/09/2022, a review of 2021 and 2022 proficiency testing records revealed that three of six attestation statements had been signed by the hospital medical director as shown below, but the individual did not meet the regulatory requirements of a laboratory director as stated at 493.1405: (a) First 2022 Chemistry Miscellaneous Event - signed on 05/05/2022 (b) Second 2022 Chemistry Core Event - signed on 05/26/2022 (c) Second 2022 Microbiology Event -

	signed on 06/22/2022 (2) The records were reviewed with the laboratory manager and technical consultant. Both stated on 08/09/2022 at 01:30 pm, the attestation statements, as shown above, had been signed and dated by an individual who did not meet the regulatory qualification requirements of a laboratory director.
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, quality control package inserts, and interview with the laboratory manager and technical consultant, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure calibration verification procedures had been performed every six months for Hemoglobin A1c testing performed on the Bio-Rad DC-10 analyzer. Refer to D5439; (2) The laboratory director failed to ensure the laboratory had control procedures that monitored the accuracy and precision of the testing process; and that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for CKMB, Troponin I, PSA, and TSH testing for seven of seven months. Refer to D5441; (3) The laboratory director failed to ensure the laboratory performed two levels of quality control materials four of five days of patient Troponin I and CKMB testing reviewed and two of 21 days of patient Hemoglobin A1c testing reviewed. Refer to D5447; (4) The laboratory director failed to ensure the laboratory performed a negative and positive control material 32 of 34 days of patient urine drug screen testing and 34 of 35 days of qualitative serum pregnancy testing. Refer to D5449; (5) The laboratory director failed to ensure the laboratory followed the manufacturer's specifications for Bio-Rad Liquichek Diabetes control materials for two of two lot numbers. Refer to D5479; (6) The laboratory director failed to ensure the laboratory performed one sample of control material each 8 hours of patient blood gas testing using a combination of control materials that include both low and high values on each day of testing for 13 of 18 patients reviewed. Refer to D5537; (7) The laboratory director failed to ensure the laboratory had a system that twice a year evaluated and defined the relationship between test results using different methodologies for two of two test methods. Refer to D5775.
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, quality control package inserts, and interview with the laboratory manager and technical consultant, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, quality control package inserts, and interview with the laboratory manager and technical consultant, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure that verification procedures were adequate to determine the performance characteristics. Refer to D6040; (2) The technical consultant failed to ensure a quality control program had been estabilised to which ensured the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042.
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 and technical consultant, 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 performance specifications had been demonstrated for one of two new test methods. Refer to D5421.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

	This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, quality control package inserts, and interview with the laboratory manager and technical consultant, the technical consultant failed to establish a quality control program which ensured the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure the laboratory had control procedures that monitored the accuracy and precision of the testing process; and that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for CKMB, Troponin I, PSA, and TSH testing for seven of seven months. Refer to D5441; (2) The technical consultant failed to ensure two levels of quality control materials had been performed four of five days of patient Troponin I and CKMB testing reviewed and two of 21 days of patient Hemoglobin A1c testing reviewed. Refer to D5447; (3) The technical consultant failed to ensure a negative and positive control material had been performed 32 of 34 days of patient urine drug screen testing and 34 of 35 days of qualitative serum pregnancy testing. Refer to D5449; (4) The technical consultant failed to ensure the laboratory followed the manufacturer's specifications for Bio-Rad Liquichek Diabetes control materials for two of two lot numbers. Refer to D5479; (5) The technical consultant failed to ensure the laboratory performed one sample of control material each 8 hours of patient blood gas testing using a combination of control materials that include both low and high values on each day of testing for 13 of 18 patients reviewed. Refer to D5537.