Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0445888	05/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Hermann Area District Hospital	509 West 18th Street, Hermann, MO	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel policy, personnel records, and interview with the technical supervisor (TS) #1, the laboratory failed to establish and follow written policies to assess competency for five of five testing personnel during 2019, 2020 and to date May 12,2021. Findings: 1. The "Orientation, Teaching and Competency" policy states, "Competency is verified by the laboratory director or supervisor. Routine competency is verified on an annual basis, usually in conjunction with performance appraisal. The form must be signed by the employee and laboratory director." The policy failed to address semiannual competency evaluations during the first year individuals test patient specimens. (493.1451) 2. The laboratory director or supervisor failed to evaluate and document annual competency evaluations for testing personnel during 2019, 2020, and to date May 12, 2021. (Refer to D6128) 3. Interview with TS #1 on May 12, 2021 at 3:15 PM confirmed the laboratory failed to follow the written policy for conducting annual competency and failed to establish a policy for conducting semiannual competency during the first year individuals test patient specimens.
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 lack of blood bank testing procedures, lack of chemistry test procedures, observation of the urinalysis centrifuge, review of function check records, review of Ortho Diagnostics Vitros 5600 quality control (QC) records, review of Sysmex CA-600 Prothrombin Time (PT) QC records, review of the laboratory's "Quality Control Monitoring" procedure, review of hematology records, review of the "Prothrombin Time" procedure, review of Siemens Dade Innovin package insert, review of Sysmex CA-600 analyzer, review of manufacturer's instructions, review immunohematology records, and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to provide a written procedure manual for all tests, assays, and examinations performed by the laboratory (Refer to D5401); the laboratory failed to define a protocol to verify the urine centrifuge was operating at the appropriate speed for obtaining urine sediment for microscopic examination (Refer to D5435); the laboratory failed to establish criteria for acceptability of control materials providing quantitative results (Refer to D5469); the laboratory failed to document the quality of staining materials each day of use for manual differentials (Refer to D5473); the laboratory failed to ensure alkaline phosphatase (ALP) and troponin-I QC met criteria for acceptability before reporting patient results (Refer to D5481); the laboratory failed to include two levels of control material each 8 hours of operation for PT, the laboratory failed to verify the correct International Sensitivity Index (ISI) value was being used for calculating the INR value (Refer to D5545); and the laboratory failed to follow manufacturer's instructions for incubator temperature verification (Refer to D5551).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on lack of blood bank testing procedures, lack of chemistry test procedures, and interview with the technical supervisor (TS) #1, the laboratory failed to provide a written procedure manual for all tests, assays, and examinations performed by the laboratory. Findings: 1. Review of procedures showed no procedures for blood bank or chemistry testing. 2. Interview with the TS #1 on May 12, 2021 at 1:30 PM confirmed the laboratory could not provide a written procedure manual for all tests, assays, and examinations performed by the laboratory.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a

	function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation of the urinalysis centrifuge, review of function check records, and interview with the technical supervisor (TS) #1, the laboratory failed to define a protocol to verify the urine centrifuge was operating at the appropriate speed for obtaining urine sediment for microscopic examination. Findings: 1. Observation of the urinalysis centrifuge revealed the centrifuge was operating at a speed of 1500 RPMs. 2. Review of function check records revealed no documentation to show the laboratory verified the urine centrifuge speed of 1500 RPMs. 3 Interview with TS #1 on May 12, 2021 at 3:15 PM confirmed the laboratory failed to define a protocol to verify the RPMs required for obtaining urine sediment.
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 Ortho Diagnostics Vitros 5600 quality control (QC) records, Sysmex CA-600 Prothrombin Time (PT) QC records, the laboratory's "Quality Control Monitoring" procedure, and interview with the technical supervisor (TS) #1, the laboratory failed to establish criteria for acceptability of control materials providing quantitative results. Findings: 1. Review of the Ortho Diagnostics Vitros 5600 QC records, Sysmex CA-600 PT QC records and the laboratory's "Quality Control Monitoring" procedure showed the laboratory did not establish and define statistical parameter criteria (mean and standard deviations) for acceptability of quantitative QC results reported on the chemistry and coagulation analyzers. 2. Interview with the TS #1 on May 12, 2021 at 3:00 PM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)

	(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of hematology records and interview with the technical supervisor (TS) #1, the laboratory failed to document the quality of staining materials each day of use for manual differentials for 2019, 2020 and to date May 12, 2021. Findings: 1. Review of hematology records revealed the laboratory failed to document the quality of staining materials each day of use for manual differentials. 2. Interview with TS #1 on May 12, 2021 at 3:15 PM confirmed the laboratory failed to document the quality of the manual differential stain each day of use.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Ortho Diagnostics Vitros 5600 quality control (QC), and interview with the technical supervisor (TS) #1, the laboratory failed to ensure alkaline phosphatase (ALP) and troponin-I QC met criteria for acceptability before reporting patient results for 33 of 73 testing days in March, April, and to date May 12, 2021. Findings: 1. Review of QC showed the laboratory's acceptable established ranges as: ALP Level 1 Lot # P7690 as 103 - 116 ALP Level 2 Lot # T7911 as 439 - 478 Troponin-I Level 3 Lot # CXL21123 as 30.537 - 34.463 2. Review of ALP Level 1 QC showed: March 13, 2021 Level 1 QC result of 102 March 26, 2021 Level 1 QC result of 101 March 27, 2021 Level 1 QC result of 100 April 15, 2021 Level 1 QC result of 102 April 28, 2021 Level 1 QC result of 102 April 29, 2021 Level 1 QC result of 102 May 3, 2021 Level 1 QC result of 102 May 6, 2021 Level 1 QC result of 102 May 7, 2021 Level 1 QC result of 100 May 9, 2021 Level 1 QC result of 102 3. Review of ALP Level 2 QC showed: March 3, 2021 Level 2 QC result of 438 March 4, 2021 Level 2 QC result of 436 March 8, 2021 Level 2 QC result of 437 March 15, 2021 Level 2 QC result of 438 March 18, 2021 Level 2 QC result of 429 March 20, 2021 Level 2 QC result of 437 March 21, 2021 Level 2 QC result of 433 March 23, 2021 Level 2 QC result of 435 March 28, 2021 Level 2 QC result of 431 April 10, 2021 Level 2 QC result of 436 April 11, 2021 Level 2 QC result of 436 April 12, 2021 Level 2 QC result of 426 April 13, 2021 Level 2 QC result of 430 April 14, 2021 Level 2 QC result of 436 April 21, 2021 Level 2 QC result of 436 April 30, 2021 Level 2 QC result of 432 May 1, 2021 Level 2 QC result of 433 May 2, 2021 Level 2 QC result of 438 May 3, 2021 Level 2 QC result of 431 May 4, 2021 Level 2 QC result of 429 May 9, 2021 Level 2 QC result of 437 4. Review of Level 3 troponin-I QC showed: April 15, 2021 Level 3 troponin-I QC result of 34.600 April 21, 2021 Level 3 troponin-I QC result of 30.300 April 29, 2021 Level 3 troponin-I QC result of 29.600 April 30, 2021 Level 3 troponin-I QC result of 30.300 May 1, 2021 Level 3 troponin-I QC result of 30.500 May 3, 2021 Level 3 troponin-I QC result of 30.400 May 5, 2021 Level 3 troponin-I QC result of 29.900 May 6, 2021 Level 3 troponin-I QC result of 30.100 May 7, 2021 Level 3 troponin-I QC result of 30.300 May 8, 2021

	Level 3 troponin-I QC result of 29.600 May 9, 2021 Level 3 troponin-I QC result of 30.200 May 10, 2021 Level 3 troponin-I QC result of 30.100 May 11, 2021 Level 3 troponin-I QC result of 30.500 4. Interview with TS #1 on May 12, 2021 at 12:00 PM confirmed the laboratory failed to ensure alkaline phosphatase (ALP) and troponin-I QC met criteria for acceptability before reporting patient results.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the "Prothrombin Time (PT)" procedure, Sysmex CA-600 PT quality control (QC) records, Siemens Dade Innovin package insert, Sysmex CA-600 analyzer, and interview with the technical supervisor (TS) #1, the laboratory failed to include two levels of control material each 8 hours of operation for PT for 3 of 73 patient testing days in March, April and to date May 12, 2021 and failed to verify the correct International Sensitivity Index (ISI) value was being used for calculating the INR value. Findings: 1. Review of the PT procedure states that "controls should be tested at the initiation of testing, upon reagent changes and at least once each 8 hour shift". 2. Review of Sysmex CA-600 PT QC showed QC was not performed every 8 hours on April 16, 2021. Acceptable PT QC was performed on April 15, 2021 at 9:18 PM and not again until April 16, 2021 at 9:06 PM. 3. Review of Sysmex CA-600 PT QC showed QC was not performed every 8 hours on April 28, 2021. Acceptable PT QC was performed on April 28, 2021 at 5:16 AM and not again until April 29, 2021 at 5:32 AM. 4. Review of Sysmex CA-600 PT QC showed QC was not performed every 8 hours on May 4, 2021. Acceptable PT QC was performed on May 4, 2021 at 4:27 AM and not again until May 5, 2021 at 2:03 PM. 5. Review of the Siemens Dade Innovin package insert lot #549762 expiration 10-31-2022 showed the ISI value as 1.02 for Sysmex CA-600 analyzer. 6. Review of the Sysmex CA-600 analyzer showed Siemens Dade Innovin lot# 549762 currently in use onboard the analyzer with an ISI value as 1.04. The laboratory was unable to provide documentation of when Siemens Dade Innovin lot# 549762 was put into use. 7. Interview with the TS #1 on May 12, 2021 at 10:00 AM confirmed the laboratory failed to include two levels of control material each 8 hours of operation for PT and failed to verify the correct ISI value was being used for calculating the INR value.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed,

	as specified in this section. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, immunohematology records, and interview with the technical supervisor (TS) #1, the laboratory failed to follow manufacturer's instructions for incubator temperature verification during 2019, 2020 and to date May 12, 2021. Findings: 1. The manufacturer's instructions for incubator temperature verification states,"Fluid temperature measurements should be made with an unused card and a calibrated thin wire digital meter. Temperature must read 37 degrees C. +/- 2 degrees C." 2. Review of immunohematology records showed the laboratory failed to verify the temperature of the incubator used for antibody detection and extended crossmatch procedures. 3. Interview with TS #1 on May 12, 2021 at 3: 15 PM confirmed the laboratory failed to verify the temperature of the incubator as stated in the manufacturer's instructions.
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 "Quality Control Monitoring" procedure, Ortho Diagnostics Vitros 5600 quality control (QC), Sysmex CA-600 Prothrombin Time (PT) quality control QC records, and interview with the technical supervisor #1 (TS), the laboratory failed to establish written procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. Findings: 1. Review of the "Quality Control Monitoring" procedure states "It is the policy of this laboratory that no tests will be released unless proper QC has been performed and verified to be within established ranges." The procedure did not define what established ranges meant and did not include an ongoing mechanism to monitor and assess QC that did not fall within established ranges. 2. Review of Ortho Diagnostics Vitros 5600 QC showed the laboratory failed to ensure alkaline phosphatase (ALP) and troponin-I QC were within established ranges before reporting patient results for 33 of 73 testing days in March, April and to date May 12, 2021. 3. Review of Sysmex CA-600 PT QC showed QC was not performed every 8 hours for 3 of 73 testing days in March, April and to date May 12, 2021. 4. Interview with the TS #1 on May 12, 2021 at 12:30 PM, the TS stated "they follow Westgard rules for quality control." The laboratory was unable to provide documentation of an established policy stating that Westgard rules should be followed for QC. 5. Interview with the TS #1 on May 12, 2021 at 12:30 PM confirmed the laboratory failed to establish written procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests

	and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of Complete Blood Count (CBC) procedure, CBC patient report, and interview with the technical supervisor #1 (TS), the laboratory failed to ensure the CBC procedure reference ranges matched the reference ranges on the CBC patient report. Findings: 1. Review of the CBC procedure showed the reference ranges as: White blood cell count (WBC): Male 4.0 - 11.0 Female 4.0 - 11.0 Red blood cell count (RBC): Male 4.40 - 6.30 Female 4.20 - 5.50 Hemoglobin (Hgb): Male 14.0 - 18.0 Female 12.0 - 16.0 Hematocrit (Hct): Male 41 - 51% Female 37 - 47% Mean corpuscular volume (MCV): Male 80.0 - 97.0 Female 80.0 - 97.0 Red cell distribution width (RDW): Male 11.6 - 16.5 Female 11.6 - 16.5 2. Review of the CBC patient report showed the reference ranges as: WBC: Male 3.5 - 10.5 Female 3.5 - 10.5 RBC: Male 4.32 - 5.72 Female 3.90 - 5.03 Hgb: Male 13.5 - 17.5 Female 12.0 - 15.5 Hct: Male 38.8 - 50.0% Female 34.9 - 44.5% MCV: Male 81.2 - 95.1 Female 81.6 - 98.3 RDW: Male 11.8 - 15.6 Female 11.9 - 15.5 3. Interview with the TS #1 on May 12, 2021 at 1:30 PM confirmed that the CBC procedure reference ranges did not match the CBC patient report reference ranges.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of verification procedures, proficiency testing records for 2019 and 2020, quality control (QC) program, procedure manuals, and interviews, the laboratory director (LD) failed to provide overall management and direction of the laboratory. The LD failed to ensure verification procedures used for the Vitros 5600 chemistry analyzer and the Rapid Point blood gas analyzer were adequate (Refer to D6086); failed to ensure all proficiency testing reports received were reviewed by appropriate staff and evaluated (Refer to D6091); failed to ensure an approved corrective action plan is followed when any proficiency testing result is unacceptable or unsatisfactory (Refer to D6092); failed to maintain the QC program (Refer to D6093) and failed to ensure approved procedure manuals were available to testing personnel (Refer to D6106).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 review of chemistry records and interview with the technical supervisor (TS) #1, the laboratory director failed to ensure verification procedures were adequate for 36 of 36 analytes performed on the Vitros 5600 chemistry instrument and 4 of 4

	analytes performed on the Rapid Point blood gas instrument both introduced for patient testing in July 2020. Findings: 1. Review of chemistry records revealed no documentation to show verification procedures for the Vitros 5600 and Rapid Point blood gas instruments were adequate, reviewed and approved by the laboratory director to determine the accuracy, precision, reportable range and reference range verification. The test menu shows the laboratory performs Albumin, Alk Phos, ALT, Amy, AST, Vitamin B12, BNP, Calcium, Cholesterol, CK, CK-MB, Chloride, Creatinine, HDL, TIBC, CO2, Iron, Folate, Free T4, Gentamycin, GGTP, Glucose, HBA1C, Potassium, Lipase, MALB, Myoglobin, Phosphorus, T.Bili, Total Protein, Troponin I, TSH, Vitamin D, Urea Nitrogen, Uric and Vancomycin on the Vitros 5600 instrument. The test menu shows the laboratory performs pH, pCO2, pO2 and oxygen saturation on the Rapid Point blood gas instrument. 2. Interview with the TS #1 on May 12, 2021 at 3:15 PM confirmed no documentation was available to show the laboratory director evaluated the verification procedures prior to patient testing.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of endocrinology proficiency testing (PT) records and interview with the technical supervisor (TS) #1, the laboratory director failed to ensure appropriate staff evaluated ungraded PT results for four of five Free Thyroxine samples in the second event of 2019. Findings: 1. Review of endocrinology PT results for 2019 second event Free Thyroxine revealed samples CH-07, CH-08, CH-09, and CH-10 were not graded by the PT provider. The laboratory did not have documentation to show appropriate staff evaluated the ungraded Free Thyroxine results in the second event of 2019. 2. Interview with TS #1 on May 12, 2021 at 3:15 confirmed the laboratory director failed to ensure appropriate staff evaluated the ungraded results. 44735 Based on review of the 2020 proficiency testing (PT) records and interview with the technical supervisor (TS) #1, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. Review of the chemistry core PT records for the second PT testing event of 2020 showed the laboratory obtained a not graded result for cardiac marker-not terminal (NT) proB-type natriuretic peptide (BNP) test. The laboratory could not provide documentation to show appropriate staff evaluated the not graded results to identify any problems that may require corrective action. 2. Review of microbiology PT records showed the laboratory director failed to document review of the evaluation report obtained for the microbiology third PT event in 2020. 3. Interview with TS #1 on May 13, 2021 at 3:10 PM confirmed, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed

	when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the 2020 proficiency testing (PT) records and interview with the technical supervisor (TS) #1, the laboratory director failed to ensure an approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory. Findings: 1. Review of 2020 chemistry core- second event PT record showed the laboratory obtained an unacceptable result for specimens: BG-06 analyte partial pressure of oxygen (pO2) on the RapidPoint 405 blood gas analyzer BG-08 analytes partial pressure of carbon dioxide (pCO2), pH, and pO2 on the RapidPoint 405 blood gas analyzer CM-07 analyte myoglobin 2. Review of 2020 hematology /coagulation- second event PT record showed the laboratory obtained an unacceptable result for specimens: XE-07 analyte red cell distribution width (RDW) on the Sysmex XN-550 analyzer XE-09 analyte white cell count on the Sysmex XN-550 analyzer 3. Review of 2020 microbiology- second and third events PT record showed the laboratory obtained an unacceptable result for specimens: 2020 Microbiology- 2nd Event GS-09 analyte gram stain GS-10 analyte gram stain 2020 Microbiology- 3rd Event GS-11 analyte gram stain morphology GS-12 analyte gram stain GS-14 analyte gram stain 4. No corrective action documentation was available to show the laboratory investigated the unacceptable PT results. 5. Interview with the TS #1 on May 12, 2021 at 3:00 PM confirmed the laboratory director failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the quantity control (QC) program, QC records for 2021, and interview with the technical supervisor (TS) #1, the laboratory director failed to maintain the QC program for 2019, 2020 and to date May 12, 2021. Findings: 1. The written "Quality Control Monitoring" program states, "Quality Control is the bedrock of all laboratory procedures. It is the policy of this laboratory that no tests will be released unless proper QC has been performed and verified to be within established ranges. Ideally, once per quarter, preferably once per month the laboratory director (technical supervisor) will review the Levy-Jennings charts for all numeric analytes to see if adjustments to acceptable ranges must be made." The "Quality Control Monitoring" program (policy) did not include a policy defining established ranges or acceptable statistical parameters (mean and standard deviations) for controls providing quantitative results. 2. Review of QC records from the laboratory information system (LIS) for 2021 revealed the laboratory was unable to generate cumulative reports/ Levy-Jennings charts necessary to evaluate QC results, shifts, trends and acceptable standard deviations for monthly or quarterly review for 2019, 2020 and to date May 12, 2021. 3. On interview with TS #1 on May 14, 2021 at 3:15 PM, the TS said the LIS used to generate QC results was difficult for evaluating limits of acceptability. Interview confirmed the laboratory director failed to maintain the QC program.

D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals and interview with the technical supervisor #1, the laboratory failed to ensure an approved procedure manual was available to testing personnel performing blood gas testing. Findings: 1. The laboratory did not have documentation to show the laboratory director approved the Rapid Point 500c blood gas procedure manual.The laboratory performs ph, pCo2, pO2 and oxygen saturation on the Rapid Point 500c blood gas analyzer. 2. Interview with technical supervisor #1 on May 12, 2021 at 3:15 PM confirmed, there was no documentation to show an approved procedure manual was available for blood gas testing on the Rapid Point 500c blood gas instrument.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, 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. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the technical supervisor (TS) #1, the TS failed to evaluate and document competency/performance for five of five testing personnel at least annually during 2019, 2020 and to date May 12, 2021 Findings: 1. Review of personnel records revealed the technical supervisor did not evaluate competency/performance for testing personnel #1, #2, #3, #4 and #7 performing patient testing during 2019, 2020 and to date May 12, 2021. 2. Interview with TS #1 on May 12, 2021 at 3:15 PM confirmed competency/performance evaluations were not conducted at least annually.