Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	11D0021848	04/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dodge County Hospital Laboratory	901 Griffin Avenue, Eastman, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on April 19 - April 20, 2022 . The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The laboratory was determined to be in Immediate Jeopardy due to the laboratory's inability to demonstrate compliance in the speciality of Chemistry, subspecialty of Blood Gas (Ph, PO2, PCO2). The following deficiencies were cited:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on document review and staff interviews, the laboratory failed to enroll in Proficiency Testing (PT) for the subspecialty of Blood Gas (analytes of PH #315, PO2 #325, and PCO2 #335), resulting in Immediate Jeopardy. Findings include: 1. Review of the CMS CASPER Report 096D revealed the laboratory did not participate in American Proficiency Institute (API) PT for the following events: 2021 #1, 2021 #2, 2021 #3, and 2022 #1 in the subspecialty of Blood Gas (analytes of PH #315, PO2 #325, and PCO2 #335). 2. Review of documention provided to the survey team revealed the Blood Gas, General Supervisor, did not order PT for PH #315, PO2 #325, or PCO2 #335 in 2021 thru testing event #1 of 2022. 3. Interviews with staff #2 and staff #13 (CMS 209) via telephone, on 4/19/22, at approximately 2:45 PM, in the

	Technical Supervisor and General Supervisor's office, confirmed the the PT samples were not ordered or analyzed from 2021 - 2022 event #1.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: The laboratory failed to maintain satisfactory proficiency testing (PT) performance for Compatibility Testing #895 in 2020 event #3 and in 2021 event #2 resulting in the unsuccessful performance for Compatibility Testing #895. Findings include: Refer to D2173
D2173	COMPATIBILITY TESTING CFR(s): 493.863(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on proficiency testing desk review, using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153, and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in Compatibility Testing #895, in 2020 event #3 and 2021 event #2 , resulting in the first unsuccessful performance. Findings include: 1. Desk review of Casper Reports 153 and 155 revealed the laboratory failed analyte #895 Compatibility Testing on event #3 of 2020 with a score of 80% and event#2 of 2021 with a score of 60%. 2. Desk review of the laboratory's proficiency testing reports, from American Proficiency Institute (API), confirmed the laboratory failed Compatibility Testing #895, on 2020 Event #3 and 2021 Event #2, resulting in the first unsuccessful performance.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230

	Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the Quality Assurance (QA) Policy and staff interview, the laboratory failed to provide documentation of QA monitoring and evaluation of the overall quality of the general laboratory systems. There were no documents for the years 2020, 2021, or 2022. Reference: D5293
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the Quality Assurance (QA) Policy and staff interview, the laboratory failed to provide documentation of Quality Assessment review for years 2020, 2021, or 2022 thru the date of survey. Findings: 1. After review of the QA Policy, the Laboratory Manager (LM) was asked to provide documentation of the Quality Assessment reviews for years 2020, 2021, and 2022 documents. The LM stated that there were no Quality Assessment documents available. 2. Interview with the LM, in the managers office, and the Technical Supervisor, via phone, on April 20, 2022, at approximately 1:45 pm, confirmed the aforementioned statement.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the Blood Gas GEM Premier 3000 Operators Manual, lack of quantitative quality control (QC) documents for PH, PO2, & PCO2, review of the IL ACL TOP 300CTS Coagulation analyzer manual, failure to perform verification of Platelet Poor Plasma samples for Coagulation testing, observation of expired reagents in the Chemistry and Microbiology refrigerators, and staff interviews, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as required contributing to the Immediate Jeopardy

	Determination. Findings include: For details refer to: D5413, D5417, D5421, D5429, D5437, D5445, and D5465
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on document review of the IL ACL TOP 300CTS Coagulation (Coag) Analyzer documents, the laboratory failed to provide documentation for the Platelet Poor Plasma procedure, to verify speed and time of centrifugation for coag. specimens for years 2020 or 2021. Findings: 1. Review of the coag. documents for years 2020 and 2021, revealed there was no documentation to support the Platelet Poor Plasma procedure was verified for the correct speed and time on the centrifuge, in the processing of coag.specimens, for Platelet Poor Plasma. 2. Interview with the general supervisor (CMS 209 #3) and phone interview with the Technical Supervisor (CMS 209 #2), on April 20, 2022, at approximately 2:30 pm, in the Laboratory Manager's office, confirmed the aforementioned statement.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation during the tour of the laboratory, and reviewing reagents, solutions, culture media, control materials, calibration materials, and other supplies, the laboratory had three expired materials in the Chemistry (Chem) Refrigerator and the Microbiology Media/sample (Micro) storage refrigerator. Findings: 1. In the Chem Refrigerator, there was a box of Access Sample Diluent A, with a expiration date of 3-31- 2022 on the box. The box did not have any markings on it as to the diluent was not bing used for patient testing. 2. In the Chem Refrigerator, there was a DAT (THC) calibrator #4, used to calibrate the Drug of Abuse Tetrahydrocannabinol, with an expiration date of 10-31-2021. 3. In the Micro refrigerator, observed a box of Becton Dickinson, BBL CFinase Beta-Lactamase Detection Discs with an expiration date of 03/31/2022. 4. Interview with the laboratory manager on April 20, 2022, at approximately 3 pm, in the Core Lab area, confirmed the above aforementioned statements.
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 staff interview and review of Blood Gas GEM Premier 3000 analyzer, installed on February 4, 2021, the laboratory failed to review, evaluate, or approve the verification data. Findings include: 1. Review of the installation data provided for the GEM Premier 3000 analyzer (Serial Number 21014834), installed on February 4, 2021, revealed that the laboratory failed to review, evaluate, or approve the verification data. The data was not approved by the lab director before patient testing was performed. 2. Interview with the General Supervisor (CMS 209 #3), on April 19, 2022, at approximately 3pm, in the lab office, confirmed the above aforementioned statement.
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 review of the Blood Gas GEM Premier 3000 Instrument Manual, and staff interview, the laboratory failed to document maintenance, as defined by the manufacturer, or with at least the frequency specified by the manufacturer for years 2021 and 2022 thus far. Findings: 1. Review of the labortaory documents reveals the laboratory failed to provide documentation of maintenance for years of 2020, 2021, or 2022. 2. Interview with the General Supervisor (CMS 209 #3) , on April 20, 2022, at approximately 2:30 pm, in the Blood Gas Laboratory, confirmed the aforementioned statement.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: Based on the lack of the GEM Premier 3000 Blood Gas (BG) analyzer calibration documents, review of pipette calibration records, and staff interview, the laboratory failed to calibrate the GEM Premier 3000 analyzer and all pipettes at the frequency required by the manufacturer. Findings include: 1. Review of the BG documents provided, revealed the lack of calibrations performed in 2020, 2021, and to date 2022. There were no records provided for the calibrations of the GEM Premier 3000 blood gas (BG) analyzer. 2. Review of the pipette calibration records revealed pipette #9, #10, and #11 were not calibrated in the year 2020. 3. Interview with the General Supervisor (CMS 209 #3), on April 19, 2022, at approximately 2:45 pm in the lab office, confirmed the aforementioned statements.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) document review and staff interview, the lab failed to perform control procedures using the number and frequency specified by the manufacturer in the subspecialty of Blood Gas (BG). Findings include: 1. QC record review revealed the laboratory failed to provide QC documentation, at the time of survey, for August -December 2020, January - December 2021, and January 2022 to survey date. Last QC documentation was on 07/27/2020. 2. Documention provided to the survey team, on 4/19/22, by the General Supervisor of the Blood Gas Lab (staff #13 on the CMS 209), stated "New blood gas machine installed in February of 2021. Control not done due to internal controls done. Control done 1st part of 2020 but stopped due to Covid and could not keep up with the demand of ABGs and not enough cartridge supplies during shortages". 3. Phone interview with the General Supervisor of the Blood Gas Lab (staff #13 on the CMS 209), in the main laboratory office, on 4/19/22, at approximately 2:45 p.m., confirmed the lack of QC for the aforementioned quantitative BG tests for 2020, 2021, and 2022 thus far.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(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-- Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Blood Gas (BG) quality control records, documented letter, and staff interview, the laboratory failed to perform and document the required quality

	controls (QC) for quantitative testing in blood gases (PH, PO2, PCO2). Findings include: 1. QC record review revealed the laboratory failed to provide QC documentation, at the time of survey, for August -December 2020, January - December 2021, and January 2022 to survey date. Last QC documentation is 07/27 /2020. 2. Letter provided to the survey team on 4/19/22 from the general supervisor of the blood gas lab (staff #13 on the CMS 209) states "New blood gas machine installed in February of 2021. Control not done due to internal controls done. Control done 1st part of 2020 but stopped due to Covid and could not keep up with the demand of ABGs and not enough cartridge supplies during shortages". 3. Phone interview with the General Supervisor of the Blood Gas Lab (staff #13 on the CMS 209), in the main laboratory office, on 4/19/22, at approximately 2:45 p.m., confirmed the lack of QC for aforementioned quantitative BG tests for 2020, 2021, and 2022 thus far.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of Urinalysis (UA) quality control (QC) records and staff interview, the lab failed to document corrective actions when QC exceeded acceptable limits. Findings include: 1. Review of abnormal UA QC records revealed the specific gravity QC exceeded limits 1 of 30 days reviewed in April 2020; 12 of 50 days reviewed for January-April 2022 without corrective actions noted. 2. Review of normal UA QC records reveals the Specific gravity QC exceeded limits 9 of 30 days reviewed in April 2020; 24 of 61 days reviewed for January-April 2021; and 29 of 50 days reviewed for January-April of 2022 without corrective actions noted. 3. Interview with the General Supervisor #3 (CMS 209 form), on 4/20/22, at approximately 1 PM, in the lab office, confirmed the corrective actions were not documented.
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 the Quality Assessment, Quality Control, Proficiency Testing, and the Blood Gas GEM PREMIER (GP) documents, the Laboratory Director failed to provide overall management and direction in the Laboratory resulting in Immediate Jeopardy. Reference: D6079, D6088, D6091, D6093, and D6094

D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on document review and staff interviews, the lab director (LD) failed to have oversight of the blood gas (BG) lab associated with the diagnostic lab under the CLIA # 11D0021848. Findings include: 1. Review of Proficiency Testing (PT) documents revealed the LD failed to ensure the BG lab was enrolled in a PT program as required. 2. Review of the Quality Control (QC) documents revealed the LD failed to ensure the BG lab was performing QC as required and the QC program was maintained. 3. Maintenance and function checks for the Blood Gas GEM PREMIER 3000 blood gas analyzer were not available for 2021 and 2022. 4. Interview with the General Supervisor (CMS 209 #3) and a phone interview with the Technical Supervisor (CMS 209 #2) on April 20, 2022, at approximately 2:45 pm, in the Laboratory Manager's office, confirmed the above aforementioned statements.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the lack of Proficiency Testing (PT) document to review, documented letter from the Blood Gas (BG) General Supervisor, and staff interviews, the lab director failed to ensure the BG lab was enrolled in a PT program. Findings include: 1. Review of the CMS CASPER Report 096D revealed the laboratory did not participate in American Proficiency Institute (API) PT for the following events: 2021 #1, 2021 #2, 2021 #3, and 2022 #1, in the subspecialty of Blood Gas (PH #315, PO2 #325, and PCO2 #335). 2. Review of a documentation provided to the survey team revealed the General Supervisor, of Blood Gas Lab, did not order the PT for PH #315, PO2 #325, and PCO2 #335 for the year of 2021 thru event #1 of 2022. 3. Interviews with staff #2 and staff #13 (CMS 209), via telephone, on 4/19/22, at approximately 2:45 PM, in the Technical Supervisor and General Supervisor's office, confirmed the PT samples were not ordered or analyzed for 2021 - 2022 event #1.
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 proficiency testing desk review, using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153, and review of the laboratory's proficiency testing (PT) reports, the laboratory director failed to ensure the lab maintained satisfactory performance in Compatibility Testing #895, in 2020 event #3 and 2021 event #2 , resulting in the first unsuccessful occurrence. Findings include: 1. Desk review of Casper Reports 153 and 155 revealed the laboratory failed analyte #895 Compatibility Testing on event #3 of 2020 with a score of 80% and event#2 of 2021 with a score of 60%. 2. Desk review of the laboratory's proficiency testing reports, from American Proficiency Institute (API), confirmed the laboratory failed Compatibility Testing #895, on 2020 Event #3 and 2021 Event #2, resulting in the first unsuccessful performance.
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 quality control (QC) document review and staff interview, the lab failed to perform control procedures using the number and frequency specified by the manufacturer in the subspecialty of Blood Gas (BG). Findings include: 1. QC record review revealed the laboratory failed to provide QC documentation, at the time of survey, for August -December 2020, January - December 2021, and January 2022 to survey date. Last QC documentation was 07/27/2020. 2. Letter provided to the survey team, on 4/19/22, from the General Supervisor of the Blood Gas Lab (staff #13 on the CMS 209) states "New blood gas machine installed in February of 2021. Control not done due to internal controls done. Control done 1st part of 2020 but stopped due to Covid and could not keep up with the demand of ABGs and not enough cartridge supplies during shortages". 3. Phone interview with the General Supervisor of the Blood Gas Lab (staff #13 on the CMS 209), in the main laboratory office, on 4/19/22, at approximately 2:45 p.m., confirmed the lack of QC for the aforementioned quantitative BG tests for 2020, 2021, and 2022 thus far.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 Quality Assessment (QA) documents and the lack of QA monitoring documents, for the years 2020, 2021, and 2022, the Laboratory Director (LD) failed to ensure that the quality assessment programs were maintained to assure

	the quality of the laboratory services provided and to identify failure in quality as they occurred. Findings: 1. Quality Control (QC) documents for the Blood Gas GEM PREMIER 3000 blood gas analyzer were not available for Aug.- Dec 2020, 2021, and 2022 thus far. 2. American Proficiency Institute (API) Proficiency Testing (PT), documents for the Blood Gas GEM PREMIER 3000 Blood Gas Analyzer were not available for 2021 and 2022. 3. Maintenance and function checks for the Blood Gas GEM PREMIER 3000 Blood Gas Analyzer were not available for 2021 or 2022. 4. Interview with the Laboratory Manager and a phone interview with the Technical Supervisor, on April 20, 2022, at approximately 2:45 pm, in the Laboratory Manager's office, confirmed the above aforementioned statements.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on document review and staff interviews, the technical supervisor is not providing technical and scientific oversight of the blood gas laboratory, resulting in Immediate Jeopardy. For details refer to D6112
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on document review and staff interviews, the Technical Supervisor (TS) failed to provide technical and scientific oversight of the blood gas (BS) laboratory. Findings include: 1. Review of the Blood Gas GEM Premier 3000 documents revealed the laboratory failed to provide documentation of the maintenance performance for the years of 2020, 2021, or 2022. 2. Review of the BG documents revealed the lack of calibrations in 2020, 2021, and to date 2022. No records were provided for the calibrations of the GEM Premier 3000 blood gas (BG) analyzer. 3. Blood Gas QC record review revealed the laboratory failed to provide QC documentation, at the time of survey, August -December 2020, January - December 2021, and January 2022 to survey date. Last QC documentation was 07/27/2020. 4. Interviews with the General Supervisor (CMS 209 #3) and the technical supervisor (CMS 209 #2) by phone, on 4/19/22, at approximately 14:45, in the lab office, confirmed the aforementioned findings.