Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2198833	03/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Center Of Health/Out-Patient Surgery Center	9001 Summa Ave, Suite 140, Baton Rouge, LA	

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 Recertification survey was conducted March 12, 2025 at Center of Health/Out-Patient Surgery Center - CLIA ID # 19D2198833. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard level deficiencies were cited.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 (Laboratory Personnel Report) form, policies, and proficiency testing records; as well as interview with personnel, the laboratory failed to ensure proficiency testing samples were rotated among all testing personnel performing routine chemistry and hematology testing for three (3) of three (3) events reviewed. Findings: 1. Review of the laboratory's CMS-209 form revealed the following four (4) personnel served as testing personnel: a) Personnel 1 b) Personnel 2 c) Personnel 3 d) Personnel 4 2. Review of the laboratory's policy "Blood Gas Laboratory: Proficiency Testing" revealed "As feasible, the analysis of proficiency testing samples will be rotated among all testing personnel." 3. Review of the laboratory's 2024 College of American Pathologists (CAP) proficiency testing records revealed Personnel 1 performed all samples in each of the following three (3) testing events: a) AQH-A 2024 b) AQH-B 2024 c) AQH-C 2024 4. In interview on March 12, 2025 at 12:09 p.m., the Technical Consultant confirmed Personnel 1 performed all testing for the three (3) proficiency testing events in 2024 as identified above.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES

	CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with personnel, the laboratory failed to ensure the Testing Personnel signed the attestation statement for two (2) of four (4) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's College of American Pathologists (CAP) proficiency testing records revealed the Testing Personnel did not sign the attestation statement for the following two (2) testing events: a) AQH-A 2024 b) AQH-B 2024 2. In interview on March 12, 2025 at 12:09 p.m., the Technical Consultant confirmed the testing personnel did not sign the attestation statements for the PT events identified above.
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 policies, CMS-209 form, and personnel records; as well as interview with personnel, the laboratory failed to establish written policies and procedures to assess competency of the Technical Consultant. Findings: 1. Review of the laboratory's policy "Personnel Policies, Competency, & Files" revealed the laboratory did not include procedures, including, but not limited to frequency of performance of competency assessments for the Technical Consultant. 2. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed Personnel 5 served as Technical Consultant. 3. Review of personnel records for Personnel 5 revealed a competency assessment was not performed for her role as Technical Consultant. 4. In interview on March 12, 2025 at 10:24 a.m., the Technical Consultant confirmed the laboratory did not have a policy related to competency assessment of the Technical Consultant. She stated she thought a competency was performed but the laboratory could not provide documentation of performance.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with laboratory personnel, the laboratory failed to ensure laboratory policies and procedures were approved and signed by the laboratory director. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory director did

	not approve and sign all policies and procedures in use to include, but not limited to, the following policies: a) EPOC Blood Gas Quality Assurance Program b) Blood Gas Laboratory: Proficiency Testing c) Quality Control EPOC 2. In interview on March 12, 2025 at 11:48 p.m., the Laboratory Director confirmed he did not approve and sign the policies identified above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies and temperature logs and interview with personnel, the laboratory failed to document the room temperature and humidity for forty-four (44) of four hundred twenty-four (424) days reviewed. Findings: 1. Review of the laboratory's policy "Environmental Monitoring" revealed "Room temperature and humidity are monitored and documented daily in the CFH." 2. Review of the laboratory's "Environmental Monitoring Log" from January 2024 to February 2025 for the "CFH Peri Op" area revealed temperature and humidity were not documented on the following dates: January 3, 2024 January 9, 2024 January 17, 2024 January 24, 2024 February 14, 2024 February 20, 2024 February 28, 2024 March 7, 2024 March 14, 2024 March 22, 2024 March 25, 2024 April 5, 2024 April 10, 2024 April 18, 2024 April 26, 2024 April 29, 2024 May 9, 2024 May 14, 2024 May 23, 2024 May 30, 2024 June 18, 2024 June 26, 2024 July 18, 2024 July 22, 2024 July 24, 2024 August 2, 2024 August 5, 2024 August 13, 2024 August 16, 2024 August 21, 2024 August 28, 2024 September 9, 2024 September 12, 2024 September 20, 2024 September 23, 2024 September 30, 2024 October 24, 2024 October 28, 2024 November 4, 2024 November 26, 2024 November 27, 2024 November 29, 2024 December 16, 2024 February 13, 2025 3. In interview on March 12, 2025 at 1:34 p. m., Personnel 4 confirmed the laboratory did not document the temperature and humidity on the dates identified above. II. Based on review of the laboratory's policies and temperature logs and interview with personnel, the laboratory failed to document the refrigerator temperature for eleven (11) of two hundred forty-two (242) days reviewed. Findings: 1. Review of the laboratory's policy "Environmental Monitoring" revealed "On a daily basis record all refrigerator temperatures." 2. Review of the laboratory's "Environmental Monitoring Log" from January 2024 to June 2024 and November 2025 to December 2025 for the "PAE Fridge" revealed the refrigerator temperature was not documented on the following dates: April 5, 2024 April 10, 2024 April 18, 2024 April 26, 2024 May 9, 2024 May 23, 2024 May 30, 2024 June 18, 2024 June 26, 2024 November 29, 2024 December 16, 2024 3. In interview on March 12, 2025 at 3:37 p.m., Personnel 4 confirmed the laboratory did not document the refrigerator temperature on the dates identified above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)

	(d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on observation; review of the laboratory's policies, quality control records, and patient test records; as well as interview with personnel, the laboratory failed to perform quality control (QC) every thirty (28) days as required by the laboratory on the EPOC analyzer for two (2) of fourteen (14) months reviewed. Findings: 1. Observation by surveyor on March 12, 2025 at 10 a.m. during the laboratory tour revealed the laboratory utilized the EPOC analyzer for pH, CO2, pO2, Sodium, Potassium, Calcium, Glucose, Chloride, Creatinine, Blood urea nitrogen, Hematocrit, and Hemoglobin testing. 2. Review of the laboratory's Individualized Quality Control Plan (IQCP) revealed "Level 1 and Level 3 run QMonth." 3. Review of the laboratory's policy "Quality Control EPOC" revealed "Level 1, Level 3, Level A, & Level B run QMonth." 4. In interview on March 12, 2025 at 1:55 p.m., the Technical Consultant stated QC is performed every twenty-eight (28) days on the EPOC analyzer unless the due date falls on a weekend. 5. Review of the laboratory's quality control records from January 2024 through February 2025 revealed the laboratory did not perform quality control every twenty-eight (28) days as follows: a) External QC performed April 2, 2024 and May 6, 2024 (Due April 30, 2024 - six (6) days overdue) b) External QC performed May 6, 2024 and June 7, 2024 at 1353 (Due June 3, 2024 - four (4) days overdue) 6. Review of patient test records revealed the following patients were tested and reported without QC performed as required: a) Patients tested between May 1 and May 6, 2024: Patient 000102092378: May 3, 2024 Patient 000102099232: May 3, 2024 Patient 000102106864: May 3, 2024 b) Patients tested between June 4 and June 7, 2024 Patient 000102123942: June 7, 2024 Patient 000102107952: June 7, 2024 Patient 000102118606: June 7, 2024 Patient 000102094916: June 7, 2024 7. In interview on March 12, 2024 at 2:45 p.m., the Technical Consultant confirmed QC was not performed as identified above.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on observation; review of quality control (QC) records, the laboratory's policies, and patient test records; as well as interview with personnel, the laboratory

	failed to take corrective action when QC values were outside of the acceptable range for pO2 testing on the EPOC analyzer for one (1) of seventeen (17) days reviewed. Findings: 1. Observation by surveyor on March 12, 2025 at 10 a.m. during the laboratory tour revealed the laboratory utilized the Eurotrol epoc Gas-ISE Metabolites Level 1 and Level 3 quality control material on the EPOC analyzer for pH, CO2, pO2, Sodium, Potassium, Calcium, Glucose, Chloride, Creatinine, and Blood urea nitrogen testing. 2. Review of the quality control records from January 2024 revealed the laboratory did not perform complete corrective actions when QC Level 1 was outside of the acceptable range for pO2 on January 3, 2024 as follows: a) QC Level 1 Lot 266-1-B305 pO2 acceptable range 58.4 to 90.0 mmHg - pO2 resulted as 102.5 mmHg at 1: 08 p.m. - pO2 resulted as 95.5 mmHg at 2:06 p.m. 3. Further review of QC records from January 2024 revealed the next acceptable run of QC Level 1 for pO2 was on January 11, 2024 at 6:58 a.m. 4. Review of the laboratory's Individualized Quality Control Plan (IQCP) revealed "Any failure of QC, Calibration, or environmental issue will not allow patient sampling to be done." 5. Review of patient test records from January 3, 2024 to January 11, 2024 revealed the following patients were tested without acceptable QC: a) January 4, 2024: Patient 000102032410 b) January 10, 2024: Patient 00102036996 c) January 11. 2024: Patient 000102037086 6. In interview on March 12, 2025 at 2:55 p.m., the Technical Consultant confirmed patients were tested when QC was outside of the acceptable range as identified above.
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. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish complete procedures to identify issues within the analytic system. Findings: 1. Review of the laboratory policy and procedures revealed the laboratory has a quality assessment process in place; however, the following deficient practices were not identified: a) The laboratory failed to ensure laboratory policies and procedures were approved and signed by the laboratory director. Refer to D5407. b) The laboratory failed to document the room temperature and humidity for forty-four (44) of four hundred twenty-four (424) days reviewed. Refer to D5413 I. c) The laboratory failed to document the refrigerator temperature for eleven (11) of two hundred forty-two (242) days reviewed. Refer to D5413 II. d) The laboratory failed to perform quality control (QC) every thirty (28) days as required by the laboratory on the EPOC analyzer for two (2) of fourteen (14) months reviewed. Refer to D5455. e) The laboratory failed to take corrective action when QC values were outside of the acceptable range for pO2 testing on the EPOC analyzer for one (1) of seventeen (17) days reviewed. Refer to D5783.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test

	performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form and patient test records and interview with personnel, the laboratory failed to have the correct name of the Laboratory Director on the final test report for one (1) of one (1) patient reports reviewed. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the Personnel 6 served as Laboratory Director. 2. Review of the following random final test report revealed the name of the Laboratory Director on the patient report was not Personnel 6: a) December 3, 2024: MRN 05314992 3. In interview on March 12, 2025 at 3:16 p.m., the Technical Consultant confirmed the name of the Laboratory Director on the patient test report was incorrect.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (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 record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to document the room temperature and humidity for forty-four (44) of four hundred twenty-four (424) days reviewed. Refer to D5413 I. 2. The laboratory failed to document the refrigerator temperature for eleven (11) of two hundred forty-two (242) days reviewed. Refer to D5413 II.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of laboratory policy and proficiency testing reports and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Findings: 1. The laboratory failed to ensure proficiency testing samples were rotated among all testing personnel performing routine chemistry and hematology testing for three (3) of three (3) events reviewed. Refer to D2007. 2. The laboratory failed to ensure the Testing Personnel signed the attestation statement for two (2) of four (4) proficiency testing (PT) events reviewed. Refer to D2009.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and 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 record review and interview with personnel, the Laboratory Director failed to ensure that quality programs were in place to assure quality laboratory testing. Findings: 1. The laboratory failed to perform quality control (QC) every thirty (28) days as required by the laboratory on the EPOC analyzer for two (2) of fourteen (14) months reviewed. Refer to D5445. 2. The laboratory failed to establish complete procedures to identify issues within the analytic system. Refer to D5791.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were performed when deviations from the laboratory's specifications occurred. Refer to D5783.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure complete policies and procedures for assessing competency of the Technical Consultant were established. Refer to D5209.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5407.

D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to ensure proficiency testing samples were rotated among all testing personnel performing routine chemistry and hematology testing for three (3) of three (3) events reviewed. Refer to D2007. 2. The laboratory failed to ensure the Testing Personnel signed the attestation statement for two (2) of four (4) proficiency testing (PT) events reviewed. Refer to D2009. 3. The laboratory failed to document the room temperature and humidity for forty-four (44) of four hundred twenty-four (424) days reviewed. Refer to D5413 I. 4. The laboratory failed to document the refrigerator temperature for eleven (11) of two hundred forty-two (242) days reviewed. Refer to D5413 II.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (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 record review and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5445.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratorys established performance specifications; This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Technical Consultant failed to ensure corrective actions were performed when deviations from the laboratory's policies occurred. Refer to D5783.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form and personnel records and interview with personnel, the Technical Consultant failed to perform annual competency assessments in 2024 for two (2) of four (4) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed laboratory Personnel 5 was designated as Technical Consultant. 2. Review of the laboratory's 2024 personnel records for Personnel 3 and Personnel 4 revealed a competency assessment was performed by a nurse educator, but the nurse educator was not designated by the Laboratory Director as a Technical Consultant. 3. In interview on March 12, 2024 at 12:07 p.m., the Technical Consultant confirmed she did not perform the competencies identified above.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and interview with personnel, the Technical Consultant failed to ensure the assessment of test performance through previously analyzed, internal blind samples, or external proficiency testing samples for one (1) of four (4) testing personnel was performed annually in 2024. Findings: 1. Review of the laboratory's 2024 competency records for Personnel 2 revealed an annual competency assessment was performed, but the laboratory failed to provide documentation to support the performance of blind sample testing. 2. In interview on March 12, 2025 at 10:50 a.m., the Technical Consultant confirmed the personnel identified above did not have an assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples performed.