Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2181512	01/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Olhs St Mary Place Cardiopulmonary Services	One St Mary Place, Shreveport, 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 Validation Survey was performed at OLHS ST MARY PLACE CARDIOPULMONARY SERVICES - CLIA # 19D2181512 on January 26, 2023 through January 27, 2023. OLHS ST MARY PLACE CARDIOPULMONARY SERVICES was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1210 CONDITION: Routine Chemistry 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing; Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories Performing Moderate Complexity Testing, Technical Consultant
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 Testing Personnel and/or Laboratory Director signed the attestation statement for six (6) of six (6) proficiency testing (PT) events reviewed in 2021 and 2022. Findings: 1. Review of the laboratory's College of American Pathologists (CAP) proficiency testing records from 2021 and 2022 revealed the attestation statements were not signed for the following six (6) of six (6) PT events reviewed: a) SO - A 2021 Blood Oximetry: Laboratory Director did not sign and date AQ - A 2021 Critical Care Blood Gas w/ Chemistry: Laboratory Director did not sign and date b) SO - B 2021 Blood Oximetry: Laboratory Director did not sign and date AQ - B 2021 Critical Care Blood Gas w/ Chemistry: Laboratory Director did not sign and date c) SO - C 2021 Blood Oximetry: Laboratory Director did not sign and date AQ - C 2021 Critical Care Blood Gas w/ Chemistry: Laboratory Director did not sign and date d) SO - A 2022 Blood Oximetry: Laboratory Director

	and Testing Personnel did not sign and date AQ - A 2022 Critical Care Blood Gas w/ Chemistry: Laboratory Director and Testing Personnel did not sign and date e) SO - B 2022 Blood Oximetry: Laboratory Director and Testing Personnel did not sign and date AQ - B 2022 Critical Care Blood Gas w/ Chemistry: Laboratory Director did not sign and date f) SO - C 2022 Blood Oximetry: Laboratory Director and Testing Personnel did not sign and date AQ - C 2022 Critical Care Blood Gas w/ Chemistry: Laboratory Director and Testing Personnel did not sign and date 2. In interview on January 26, 2023 at 3:10 pm, Testing Personnel 11 confirmed the laboratory's personnel did not sign and date the attestation statements for the identified events above.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation by surveyor, review of laboratory policy and records as well as interview with personnel, the laboratory failed to ensure the quality of testing in the specialty of Chemistry. Findings: 1. The laboratory failed to establish complete written policies and procedures to assess competency of testing personnel. Refer to 5209. 2. The laboratory failed to establish complete policies and procedures. Refer to 5403. 3. The laboratory failed to ensure patient samples for Arterial Blood Gas testing are analzyed within thirty (30) minutes according to the manufacturer for eighty five (85) of eighty five (85) patients reviewed from December 25, 2022 through December 31, 2022. Refer to D5305. 4. The laboratory failed to perform calibration verification procedures at least every six (6) months for the Radiometer ABL 90 Flex Plus analyzer. Refer to D5439. 5. The laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Refer to D5793.
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 policy and procedure and interview with personnel, the laboratory failed to establish complete written policies and procedures to assess competency of testing personnel. Findings: 1. Review of the laboratory policy for "Blood Gas Employee Program" revealed "All employees must have documented competency before performing laboratory procedures without direct observation. If an employee does not have documentation of competency, he/she will not be allowed to work until the requirements are satisfied". 2. Further review of the laboratory policy revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling,

	processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 3. In interview on January 26, 2023 at 3:10 pm, Testing Personnel 11 confirmed the laboratory policy did not include the identified information.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the manufacturer operator's manual, instrument tapes and interview with personnel, the laboratory failed to include the specimen collection time for blood gas testing for eighty five (85) of eighty five (85) patients reviewed from December 25, 2022 through December 31, 2022. Findings: 1. Observation by surveyors during the laboratory tour on January 27, 2023 at 11:00 am revealed the laboratory utilizes the Radiometer ABL 90 Flex Plus analyzer for Arterial Blood Gas patient testing. 2. Review of the Radiometer ABL 90 Flex Plus operator's manual under "Storage and Preparation Prior to Analysis" revealed "If it is not possible to analyze the specimen immediately, analyze it within 30 minutes after collection". 3. In interview on January 27, 2023 at 11:11 am, Personnel 11 stated the laboratory does not capture the collection time so there is no way to show if the Arterial Blood Gases (ABG) are analyzed within the thirty minute time frame. 4. Review of the laboratory's instrument tapes from December 25, 2022 through December 31, 2022 revealed the laboratory did not document the collection time for Arterial Blood Gas patient testing for the following eight five (85) of eighty five (85) patients tested December 25, 2022 through December 31, 2022: a) December 25, 2022 * Patient ID 323822502 performed at 01:58 am * Patient ID 323842609 performed at 04:03 am * Patient ID 323947750 performed at 07:28 am * Patient ID 323947750 performed at 07:29 am * Patient ID 323842609 performed at 09:51 am * Patient ID 323952314 performed at 13:05 pm * Patient ID 323952314 performed at 13:06 pm * Patient ID 323842609 performed at 16:46 pm * Patient ID 322897676 performed at 17:51 pm b) December 26, 2022 * Patient ID 323822502 performed at 01:10 am * Patient ID 322897676 performed at 05:11 am * Patient ID 323842609 performed at 12:05 pm * Patient ID 323842609 performed at 12:15 pm * Patient ID 322897676 performed at 12:24 pm * Patient ID 323994938 performed at 17:28 pm *

	Patient ID 323842609 performed at 18:32 pm * Patient ID 323999558 performed at 18:36 pm * Patient ID 323822502 performed at 23:27 pm c) December 27, 2022 * Patient 322897676 performed at 00:21 am * Patient 323842609 performed at 00:28 am * Patient 322897676 performed at 02:19 am * Patient 322897676 performed at 04:56 am * Patient 322313663 performed at 05:31 am * Patient 323842609 performed at 06:17 am * Patient 324025079 performed at 08:17 am * Patient 324025079 performed at 08:18 am * Patient 323313602 performed at 10:41 am * Patient 324124968 performed at 13:15 pm * Patient 324124968 performed at 13:16 pm * Patient 324170441 performed at 15:24 pm * Patient 324170441 performed at 15:25 pm * Patient 323842609 performed at 15:57 pm * Patient 324137028 performed at 16:23 pm * Patient 324124968 performed at 17:48 pm * Patient 324172569 performed at 18:38 pm * Patient 324137028 performed at 19:59 pm d) December 28, 2022 * Patient 324209218 performed at 01:05 am * Patient 324209218 performed at 01:07 am * Patient 324210822 performed at 03:54 am * Patient 323842609 performed at 05:16 am * Patient 324211728 performed at 05:18 am * Patient 324211728 performed at 05:20 am * Patient 322897676 performed at 05:36 am * Patient 324172569 performed at 08:01 am * Patient 323822502 performed at 12:08 pm * Patient 323842609 performed at 12:12 pm * Patient 324315521 performed at 13:06 pm * Patient 324315521 performed at 13:07 pm * Patient 324172569 performed at 16:32 pm * Patient 323822502 performed at 17:48 pm * Patient 324396101 performed at 19:47 pm * Patient 324396101 performed at 19:49 pm * Patient 324365009 performed at 20:47 pm * Patient 323822502 performed at 23:52 pm e) December 29, 2022 * Patient 323822502 performed at 02:03 am * Patient 322388993 performed at 02:53 am * Patient 322288993 performed at 02:55 am * Patient 322313663 performed at 05:01 am * Patient 324397461 performed at 05:25 am * Patient 323842609 performed at 05:29 am * Patient 323822502 performed at 12:14 pm * Patient 324388593 performed at 12:24 pm * Patient 324498657 performed at 12:28 pm f) December 30, 2022 * Patient 324586150 performed at 00:35 am * Patient 323822502 performed at 08:48 am * Patient 324670824 performed at 13:25 pm * Patient 324670824 performed at 13:26 pm * Patient 324670824 performed at 13:38 pm * Patient 323842609 performed at 17:08 pm * Patient 324714546 performed at 17:51 pm * Patient 324714546 performed at 17:52 pm * Patient 324714546 performed at 18:12 pm * Patient 323822502 performed at 18:20 pm * Patient 324716286 performed at 18:30 pm * Patient 324716286 performed at 18:31 pm g) December 31, 2022 * Patient 324714546 performed at 04:57 am * Patient 322897676 performed at 04:58 am * Patient 324670824 performed at 05:03 am * Patient 322313663 performed at 05:15 am * Patient 323842609 performed at 05:28 am * Patient 323822502 performed at 05:37 am * Patient 324748639 performed at 15:12 pm * Patient 324748639 performed at 15:13 pm * Patient 323842609 performed at 17:43 pm * Patient 323822502 performed at 19:25 pm 5. In interview on January 27, 2023 at 11:11 am, Personnel 11 confirmed the laboratory did not document the collection time so therefore the laboratory could not determine if the patients identified above were analyzed within the thirty (30) minutes required by the manufacturer. 6. Review of the task 1&3 form provided to surveyor revealed the laboratory performs 15,319 ABG tests annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

	performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures as well as interview with personnel, the laboratory failed to establish complete policies and procedures. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have written procedures to include the following: a) Written instructions for arterial blood gas quality control (QC) testing to include what QC materials is utilized, how often QC is to be performed whether external and/or internal QC, and the acceptability criteria for each QC material. b) Written procedures for the acceptability criteria of specimen handling to include the monitoring of time frames from collection, receipt and processing of patient samples. 2. In interview on January 27, 2023 at 11:00 am, Personnel 11 confirmed the laboratory did not include the above identified policies.
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 observation of surveyors, review of laboratory policy and calibration records as well as interview with personnel, the laboratory failed to perform calibration

	verification procedures at least every six (6) months for the Radiometer ABL 90 Flex Plus analyzer. Findings: 1. Direct observation by surveyors during the laboratory tour on January 27, 2023 at 11:00 am revealed the laboratory utilizes two (2) Radiometer ABL 90 Flex Plus analyzer for Arterial Blood Gas (ABG) testing with the following serial numbers: a) ABL 90 Serial number: 092R0173N0010 b) ABL 90 Serial number: 092R0173N0044 2. Review of the laboratory's policy "Calibration Verification" revealed "Each blood gas, ISE, and hemoglobin analzyer will undergo calibration verification when any of the following events occur: * Six (6) month period without a Calibration Verification * Major repair * Drift in quality control that cannot be corrected with normal procedures" 3. Review of the laboratory's calibration records from 2021 and 2022 revealed the laboratory did have documentation of calibration verification performed for the following dates: a) ABL 90 (SN 092R0173N0010) performed on October 7, 2022 b) ABL 90 (SN 092R0173N0044) performed on October 4, 2022 4. Further review of the laboratory's calibration records revealed the laboratory did not have documentation of calibration verification from 2021 or April/May 2022. 5. In interview on January 27, 2023 at 11:11 am, Personnel 11 stated the laboratory performs calibration verifcation every six (6) months for both analyzers. Personnel 11 further stated he could not find the documentation for the prior calibrations. Personnel 11 confirmed the laboratory did not have documentation of calibration verification for the identified.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory policy, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. The laboratory failed to establish complete written policies and procedures to assess competency of testing personnel. Refer to 5209. 2. The laboratory failed to establish complete policies and procedures. Refer to 5403. 3. The laboratory failed to perform calibration verification procedures at least every six (6) months for the Radiometer ABL 90 Flex Plus analyzer. Refer to D5439.
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 observation by surveyors, review of laboratory policies and records as well as interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director

	failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 2. The Laboratory Director failed to ensure proficiency testing evaluations were maintained and signed by the Laboratory Director. Refer to D6018. 3. The Laboratory Director failed to ensure that a complete quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D6021. 4. The Laboratory Director failed to ensure testing personnel had appropriate training documentation prior to patient testing. Refer to D6029. 5. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6030. 6. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.
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 observation by surveyors, review of laboratory policy and records along with interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to include the specimen collection time for blood gas testing for eighty five (85) of eighty five (85) patients reviewed from December 25, 2022 through December 31, 2022. Refer to D5305. 2. The laboratory failed to perform calibration verification procedures at least every six (6) months for the Radiometer ABL 90 Flex Plus analyzer. Refer to D5439.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that 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 the laboratory's proficiency testing records and interview with personnel, the Laboratory Director failed to ensure proficiency testing evaluations were maintained and signed by the Laboratory Director. Findings: 1. The laboratory failed to ensure Testing Personnel and/or Laboratory Director signed the attestation statement for six (6) of six (6) proficiency testing (PT) events reviewed in 2021 and 2022. Refer to D2009.
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 review of laboratory records, and interview with personnel, the Laboratory Director failed to ensure that a complete quality assessment (QA) program was established to assure the quality of laboratory services provided. Findings: 1. The laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Refer to D5793.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 (Laboratory Personnel Report), personnel records and interview with personnel, the Laboratory Director failed to ensure testing personnel had appropriate training documentation prior to patient testing. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) revealed the following testing personnel performs moderate complexity testing in the specialty of Chemistry: * Personnel 1 through Personnel 11 2. Review of the personnel records from 2021 and 2022 revealed the Laboratory Director did not review the initial training for the following six (6) of eleven (11) testing personnel: a) Personnel 4 - intial training performed 05/06/2021 b) Personnel 5- initial training performed 11/02/2021 c) Personnel 6 - initial training performed 05/06/2021 d) Personnel 7 - initial training performed 09/26/2022 e) Personnel 10 - initial training performed 05/24/2022 f) Personnel 11 - initial training performed 12/08/2021 3. In interview on January 26, 2023 at 3:10 pm, Personnel 11 stated he was unaware that the Laboratory Director should perform or review the initial training for testing personnel. Personnel 11 further stated that he or the previous respiratory supervisor performed the initial trainings. Personnel 11 confirmed the intial training for the above identified testing personnel was not reviewed by the Laboratory Director.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(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 review of laboratory policies and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to establish complete written policies and procedures to assess competency of testing personnel. Refer to D5209. 2. The Technical Consultant failed to perform a competency assessment semi-annually during the first year for four (4) of eleven (11) testing personnel reviewed. Refer to D6053. 3. The Technical Consultant failed to evaluate competency annually in 2021 and 2022 for three (3) of eleven (11) testing personnel reviewed. Refer to D6054.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) 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 policy and procedure manual and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish complete policies and procedures. Refer to D5403.
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 observation by surveyor, review of laboratory policies, personnel records, and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The laboratory failed to employ a Technical Consultant for the specialty of Chemistry in which the laboratory performs moderate complexity testing. Refer to D6034. 2. The Technical Consultant failed to provide technical and scientific oversight to the

	laboratory. Refer to D6036. 3. The Technical Consultant failed to evaluate the competency assessment for ten (10) of eleven (11) Testing Personnel in 2021 and 2022. Refer to D6046. 4. The Technical Consultant failed to ensure competency assessment for testing personnel performing Arterial Blood Gas included the direct observation of the Allen's Test for ten (10) of eleven (11) testing personnel in 2021 and 2022. Refer to 6047. 5. The Technical Consultant failed to ensure competency assessments for review of test results or worksheets, quality control records, proficiency testing results, and preventive maintenance were complete for ten (10) of eleven (11) testing personnel in 2021 and 2022. Refer to D6049. 6. The Technical Consultant failed to ensure competency assessements for respiratory personnel in 2021 and 2022 included direct observation of performance of instrument maintenance and function checks for seven (7) of eleven (11) testing personnel reviewed. Refer to D6050. 7. The Technical Consultant failed to ensure review of competency assessments in 2021 and 2022 for test performance through previously analyzed, internal blind samples, or external proficiency testing samples for eight (8) of eleven (11) testing personnel reviewed. Refer to D6051. 8. The Technical Consultant failed to ensure eleven (11) of eleven (11) testing personnel were assessed for problem solving skills in 2021 and 2022. Refer to D6052. 9. The Technical Consultant failed to perform a competency assessment semi-annually during the first year for four (4) of eleven (11) testing personnel reviewed. Refer to D6053. 10. The Technical Consultant failed to evaluate competency annually in 2021 and 2022 for three (3) of eleven (11) testing personnel reviewed. Refer to D6054.
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report), personnel records and interview with personnel, the laboratory failed to employ a Technical Consultant for the specialty of Chemistry in which the laboratory performs moderate complexity testing. Finding: 1. Review of the CMS-209 form and personnel records submitted to surveyors on January 26, 2023 at 1:34 pm revealed the laboratory did not list a Technical Consultant. 2. In interview on January 26, 2023 at 3:10 pm, Personnel 11 stated he was not sure who serves in that position. Personnel 11 confirmed the laboratory did not have a Technical Consultant.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory records, and interview with

	personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to include the specimen collection time for blood gas testing for eighty five (85) of eighty five (85) patients reviewed from December 25, 2022 through December 31, 2022. Refer to D5305. 2. The laboratory failed to perform calibration verification procedures at least every six (6) months for the Radiometer ABL 90 Flex Plus analyzer. Refer to D5439.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (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. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 (Laboratory Personnel Report) form, personnel records and interview with personnel, the Technical Consultant failed to evaluate the competency assessment for ten (10) of eleven (11) Testing Personnel in 2021 and 2022. Findings: 1. Review of the laboratory's CMS-209 form revealed the laboratory has eleven (11) Testing Personnel. 2. Review of the personnel records for 2021 and 2022 revealed the competency assessments were performed by testing personnel not the Technical Consultant. 3. In interview on January 26, 2023 at 3:10 pm, Personnel 11 stated the competency assessments for 2021 were performed by the previous laboratory manager and for 2022 by Personnel 11 who is now serving as the laboratory manager. Personnel 11 confirmed the competency assessments were not performed by a qualified Technical Consultant.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of laboratory's personnel records and interview with personnel, the Technical Consultant failed to ensure competency assessment for testing personnel performing Arterial Blood Gas included the direct observation of the Allen's Test for ten (10) of eleven (11) testing personnel in 2021 and 2022. Findings: 1. Review of the personnel records from 2021 and 2022 revealed the laboratory did not document the direct observation of performance for Allen's Test for the following ten (10) of eleven (11) testing personnel: a) Personnel 1 b) Personnel 2 c) Personnel 3 d) Personnel 4 e) Personnel 5 f) Personnel 6 g) Personnel 7 h) Personnel 8 i) Personnel 9 j) Personnel 11 2. In interview on January 26, 2023 at 3:10 pm, Personnel 11 confirmed the competency assessments for the above identified testing personnel were not complete.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records,

	proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Technical Consultant failed to ensure competency assessments for review of test results or worksheets, quality control records, proficiency testing results, and preventive maintenance were complete for ten (10) of eleven (11) testing personnel in 2021 and 2022. Findings: 1. Review of personnel records for 2021 and 2022 revealed the documentation for review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance was not completed for the following ten (10) of eleven (11) personnel reviewed: a) Personnel 1: * Review worksheets 2022 * Review QC 2022 * Review PT results 2022 * Review PM records 2022 b) Personnel 2: * Review worksheets 2021 and 2022 * Review QC 2022 * Review PT results 2021and 2022 * Review PM records 2022 c) Personnel 3: * Review worksheets 2021 and 2022 * Review QC 2022 * Review PT results 2021 and 2022 d) Personnel 4: * Review worksheets 2022 * Review QC 2022 * Review PT results 2022 e) Personnel 5: * Review worksheets 2021 and 2022 * Review QC 2021 and 2022 * Review PT results 2021 and 2022 * Review PM records 2021 and 2022 f) Personnel 6: * Review worksheets 2021 and 2022 * Review QC 2022 * Review PT results 2021 and 2022 g) Personnel 7: * Review worksheets 2022 * Review QC 2022 * Review PT results 2022 * Review PM records 2022 h) Personnel 8: * Review worksheets 2022 * Review QC 2022 * Review PT results 2022 * Review PM records 2022 i) Personnel 9: * Review worksheets 2021 and 2022 * Review QC 2022 * Review PT results 2021 and 2022 j) Personnel 11: * Review PT results 2021 and 2022 * Review PM records 2021 and 2022 2. In interview on January 26, 2023 at 3:10 pm, Personnel 11 confirmed the competency assessments identified above were not completed.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on review of the competency assessment form, personnel records and interview with personnel, the Technical Consultant failed to ensure competency assessements for respiratory personnel in 2021 and 2022 included direct observation of performance of instrument maintenance and function checks for seven (7) of eleven (11) testing personnel reviewed. Findings: 1. Review of the competency assessment form from the laboratory's personnel records from 2021 and 2022 revealed the form included a column specifically for the observation of maintenance; however, the competency assessments had documentation of NA (non-applicable) for each of the seven (7) of eleven (11) personnel reviewed: a) Personnel 1: * Maintenance 2022: NA (non-applicable) b) Personnel 2: * Maintenance 2022: NA (non-applicable) c) Personnel 4: * Maintenance 2022: NA (non-applicable) d) Personnel 5: * Maintenance 2021 and 2022: NA (non-applicable) e) Personnel 7: * Maintenance 2022: NA (non-applicable) f) Personnel 8: * Maintenance 2022: NA (non-applicable) g) Personnel 11: *

	Maintenance 2021 and 2022: NA (non-applicable) 2. In interview on January 26, 2023 at 3:10 pm, Personnel 11 confirmed the above identified competency assessments were not completed.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 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 review of competency assessments in 2021 and 2022 for test performance through previously analyzed, internal blind samples, or external proficiency testing samples for eight (8) of eleven (11) testing personnel reviewed. Findings: 1. Review of the personnel records from 2021 and 2022 revealed the competency assessments did not have documentation for review of test performance through previously analyzed, internal blind samples, or external proficiency testing samples for the following eight (8) of eleven (11) personnel reviewed: a) Personnel 1: * Proficiency Testing or Blind Samples 2022 b) Personnel 2: * Proficiency Testing or Blind Samples 2021 and 2022 c) Personnel 3: * Proficiency Testing or Blind Samples 2021 and 2022 d) Personnel 4: * Proficiency Testing or Blind Samples 2022 e) Personnel 5: * Proficiency Testing or Blind Samples 2021 and 2022 f) Personnel 7: * Proficiency Testing or Blind Samples 2022 g) Personnel 8: * Proficiency Testing or Blind Samples 2022 h) Personnel 9: * Proficiency Testing or Blind Samples 2021 2. In interview on January 26, 2023 at 3: 10 pm, Personnel 11 confirmed the above identified competency assessments were not completed.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. 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 eleven (11) of eleven (11) testing personnel were assessed for problem solving skills in 2021 and 2022. Findings: 1. Review of the personnel records from 2021 and 2022 revealed the competency assessments were not documented for problem solving skills for the following ten (10) of eleven (11) personnel reviewed: a) Personnel 1: * Problem Solving 2022 b) Personnel 2: * Problem Solving 2021 and 2022 c) Personnel 3: * Problem Solving 2021 and 2022 d) Personnel 4: * Problem Solving 2022 e) Personnel 5: * Problem Solving 2021 and 2022 f) Personnel 6: * Problem Solving 2021 and 2022 g) Personnel 7: * Problem Solving 2022 h) Personnel 8: * Problem Solving 2022 i) Personnel 9: * Problem Solving 2021 and 2022 j) Personnel 11: * Problem Solving 2021 and 2022 2. In interview on January 26, 2023 at 3:10 pm, Personnel 11 confirmed there was no documentation of problem solving skills for the above identified personnel.

D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. 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 perform a competency assessment semi-annually during the first year for four (4) of eleven (11) testing personnel reviewed. Findings: 1. Review of the laboratory's personnel records revealed the laboratory did not have documentation of a semi-annual competency assessment for the following four (4) of eleven (11) testing personnel reviewed: a) Personnel 4: * No documentation for a 6 month competency (Initial performed on 05/06/2021) b) Personnel 5: * No documentation for a 6 month competency (Initial performed on 11/02/2021) c) Personnel 6: * No documentation for a 6 month competency (Initial performed on 05 /06/2021) d) Personnel 10: * No documentation for a 6 month competency (Initial performed on 05/24/2022) 2. In interview on January 26, 2023 at 3:10 pm, Personnel 11 confirmed the laboratory did not have the semi-annual competency assessments for the identified personnel.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and interview with personnel, the Technical Consultant failed to evaluate competency annually in 2021 and 2022 for three (3) of eleven (11) testing personnel reviewed. Findings: 1. Review of the personnel records from 2021 and 2022 revealed the laboratory did not have documentation of annual competency assessments for the following three (3) of eleven (11) personnel reviewed: a) Personnel 1: * No documentation for annual competency in 2021 b) Personnel 8: * No documentation for annual competency in 2021 c) Personnel 11: * No documentation for annual competency in 2022 2. In interview on January 26, 2023 at 3:10 pm, Personnel 11 confirmed the laboratory did not have annual competency documentation for the above identified personnel.