Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0463035	04/21/2025
Name of Provider or Supplier	**Street Address, City, State**	
Womans Hospital Foundation	100 Woman'S Way, 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 Validation survey was performed on April 21, 2025 at Womans Hospital Foundation, CLIA ID # 19D0463035. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 CMS-209 (Laboratory Personnel Report), policies, and personnel records; as well as interview with laboratory personnel, the laboratory failed to establish a written competency assessment policy for Technical Consultant. Findings: 1. Review of the laboratory's CMS-209 form revealed Personnel 19 and Personnel 39 served as Technical Consultants. 2. Review of the laboratory's policy "Policy on Personnel Proficiency of Staff Competency" revealed the laboratory did not include performance of competency assessment for Technical Consultant. 3. Review of personnel records for Personnel 19 and Personnel 39 revealed a competency assessment was not performed for their role as Technical Consultant. 5. In interview on April 21, 2025 at 11:24 a.m., the Respiratory Manager confirmed the laboratory's policy did not include competency assessment of the Technical Consultant and competencies for the Technical Consultants were not performed as identified above.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)

	(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on observation, review of the manufacturer's package insert and the laboratory's policies, and interview with laboratory personnel, the laboratory failed to establish the quality control procedures in place that monitor accuracy and precision detect immediate errors and errors occurring over time for Methemoglobin testing. Findings: 1. Observation by surveyor during the laboratory tour on April 21, 2025 at 9:56 a.m. revealed the laboratory utilized Eurotrol CueSee CO-OX quality control material for Methemoglobin testing on the Avoximeter analyzer. 2. Review of the manufacturer's package insert "Eurotrol CueSee CO-OX" revealed "Users are responsible to determine their own ranges based on their own test system and tolerance limits." 3. In interview on April 21, 2025 at 3 p.m., the Respiratory Manager stated the laboratory utilizes the same established acceptable QC range for each new lot and level of QC material and the acceptable range is based on three (3) standard deviations (SD). He further stated when a new lot of QC material is received by the laboratory, he runs QC thirty (30) times and calculates the mean and SD. He then compares that data to the laboratory's established acceptable QC ranges and if there is not a significant difference, he does not change the acceptable range. 4. Review of the laboratory's policy "Procedure for Quality Control Monitoring - Avox 4000" revealed "Ranges for each test are determined by Running Precision study using data from running 30 samples each of QC Control. Once a range has been established for each Level they are not adjusted unless precision study indicates a needed adjustment." 5. Further review of the laboratory's policy "Procedure for Quality Control Monitoring - Avox 4000" revealed no clinical reference to support the use of 3SD and no criteria for adjusting the ranges based on the precision study.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on observation, review of comparison studies, and interview with personnel, the laboratory failed to perform instrument comparison testing for EPOC analyzers at least twice a year. Findings: 1. Observation by surveyor during the laboratory tour on April 21, 2025 at 9:56 a.m. revealed the laboratory utilized the following sixteen (16) EPOC analyzers to perform pH, pCO2, pO2, Sodium, Potassium, Ionized Calcium, Chloride, Carbon Dioxide, Glucose, Hematocrit, Creatinine, Blood Urea Nitrogen, and Lactate testing: Serial #52032 Serial #48338 Serial #47475 Serial #52010 Serial

	#52037 Serial #29313 Serial #5193 Serial #2491 Serial #13551 Serial #28973 Serial #52655 Serial #52176 Serial #33231 Serial #52036 Serial #43835 Serial #29170 2. Review of laboratory records for the EPOC analyzers revealed the laboratory did have documentation of comparisons between the sixteen (16) analyzers for 2023 and 2024. 3. In interview on April 21, 2025 at 4:35 p.m., the Respiratory Manager confirmed the laboratory did not compare the EPOC analyzers twice annually as identified above.
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 observation, review of manufacturer's instructions, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5775.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that quality programs were in place to assure quality laboratory testing. Refer to D5441.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (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 policies and personnel records and interview with personnel, the Laboratory Director failed to ensure eight (8) of eight (8) testing personnel reviewed had appropriate training documentation prior to patient testing. Findings: 1. Review of the laboratory's policy "Orientee Competency Policy" revealed "It is the policy of Woman's Hospital's Respiratory Care Department that the orientee, Medical Director, Lab Manager, and Technical Consultant validate the orientee's competency upon the completion of the orientation program by signing the orientation check off list." 2. Review of the laboratory's personnel records revealed the Laboratory Director did not sign the initial training for the following testing personnel: a) Personnel 3 b) Personnel 4 c) Personnel 16 d) Personnel 20 e) Personnel 32 f) Personnel 35 g) Personnel 39 h) Personnel 41 3. In interview on April 21, 2025

	at 11 a.m., the Respiratory Manager confirmed the Laboratory Director did not sign the training documents for the testing personnel identified above.
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 Consultants were established. Refer to D5209.
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, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Refer to D5775.
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 observation, record review, and interview with personnel, the Technical Consultants failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5441.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) (b)(8)(iii) 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 the laboratory's policies, review of the laboratory's personnel records, and interview with personnel, the Technical Consultants failed to ensure competency assessment for testing personnel included review of quality control (QC) records for three (3) of four (4) testing personnel. Findings: 1. Review of the laboratory's policy "Policy on Personnel Proficiency of Staff Competency" revealed "It is the policy of Woman's Hospital Respiratory Care/EKG Department that all respiratory care personnel who have successfully completed orientation and/or the annual proficiency performance evaluation are evaluated for competency every 6 months for the first year, then annually." 2. Review of personnel records for testing personnel trained between March 2023 and May 2024 revealed a semi-annual and annual competency assessment was performed for the following testing personnel; however, the laboratory failed to provide documentation to support the review of quality control performance for the time period between the semi-annual assessment and subsequent annual assessment: a) Personnel 16 * Six (6) month competency performed October 2024: epoc QC - 5/7/2024 * Annual competency performed March 2025: epoc QC - Same documentation as semi-annual assessment b) Personnel 35 * Six (6) month competency performed August 2024: epoc QC - 2/19/2024, AVOX QC - 2/20/2024 * Annual competency performed January 2025: epoc and Avox QC - Same documentation as semi-annual assessment c) Personnel 39 * Six (6) month competency performed April 2024: Avox QC - 2/27/2024 * Annual competency performed September 2024: Avox QC - Same documentation as semi-annual assessment 3. In interview on April 21, 2025 at 11:15 a.m., the Respiratory Manager confirmed the laboratory did not have the documentation to support review of quality control performance as 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 policies, review of the laboratory's personnel records, and interview with personnel, the Technical Consultants failed to ensure the assessment of test performance through previously analyzed, internal blind samples, or external proficiency testing samples for four (4) of four (4) testing personnel. Findings: 1. Review of the laboratory's policy "Policy on Personnel Proficiency of Staff Competency" revealed "It is the policy of Woman's Hospital Respiratory Care /EKG Department that all respiratory care personnel who have successfully completed orientation and/or the annual proficiency performance evaluation are evaluated for competency every 6 months for the first year, then annually." 2. Review of personnel records for personnel trained between March 2023 and May 2024 revealed a semi-annual and annual competency assessment was performed for the following testing personnel; however, the laboratory did not perform a blind sample assessment for the time period between the semi-annual competency assessment and subsequent annual competency assessment: a) Personnel 16 * Six (6) month competency performed October 2024 - Blind sample: epoc 5/17/2024 API sample BG-06 *Annual competency performed March 2025 - Blind sample: Same documentation as 6 month competency b) Personnel 32 * Six (6) month competency performed June 2024 -

	Blind samples: epoc 1/12/2024 API sample BG-03, Avox 2/21/2024 CAP samplesSO-03 * Annual competency performed November 2024 - Blind samples: Same documentation as 6 month competency c) Personnel 35 * Six (6) month competency performed August 2024 - Blind samples: epoc 2/20/2024 CAP sample AQ-01, Avox 2 /20/2024 CAP samples SO-01 * Annual competency performed January 2025 - Blind samples: Same documentation as 6 month competency d) Personnel 39 * Six (6) month competency performed April 2024 - Blind samples: epoc 3/4/2024 CAP sample Hct-01, Avox 10/24/2023 CAP sample SO-11 * Annual competency performed September 2024 - Same documentation as 6 month competency 3. In interview on April 21, 2025 at 11:15 a.m., the Respiratory Manager stated his understanding of the requirement was that the blind sample performance by testing personnel at the six (6) month assessment could be used for the subsequent annual assessment. He confirmed the personnel identified above did not have an annual assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples performed as identified above.