Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 19D0860228	**(X3) Date Survey Completed** 07/11/2023
Name of Provider or Supplier Pam Health Specialty Hospital Of New Orleans	**Street Address, City, State** 3801 Bienville St, 1st Floor, New Orleans, 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 Certification survey was performed on July 11, 2023 at PAM Health Specialty Hospital of New Orleans, CLIA ID 19D0860228. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 observation by surveyor, review of quality control documents, test menu, and interview with personnel, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for blood gas testing. Findings: 1. Observation by surveyor during the laboratory tour on July 11, 2023 at 9:28 am revealed the laboratory utilizes the i-Stat 1 for blood gas testing (pH, pCO2, and pO2) with CG4+ cartridges. 2. In interview on July 11, 2023 at 9:28 am, the Cardiopulmonary Manager stated the laboratory recently switched to the CG4+ cartridges. 3. Review of the laboratory's IQCP documents revealed the following: "The external quality control material will be: 1. Level 1 and 3 aqueous controls. Monthly: External QC of each level required per cartridge type will be performed monthly on the cartridges in use on i-STAT handhelds. New lot numbers, new shipment: will be QC'd to verify that the cartridge performance was not

	affected during transportation. Each level of external liquid QC will be performed upon receipt of reagents in the Laboratory. This can be done concurrently with the required monthly QC performance." 4. Further review of the laboratory's IQCP documents revealed the laboratory did not include in-house quality control data to support the reduction of external controls to monthly. 5. In interview on July 11, 2023 at 1:22 pm, the Cardiopulmonary Manager confirmed the laboratory did not include in-house QC data to support the reduction to monthly. 6. Review of the laboratory's test menu revealed 180 blood gas tests are performed annually.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a complete quality control program was established to assure the quality of laboratory testing. Refer to D5445.
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 policies, personnel records, and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6053.
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 policies, personnel records, and interview with personnel, the Technical Consultant failed to perform a competency assessment semi-annually during the first year for two (2) of ten (10) testing personnel reviewed. Findings: 1. Review of the laboratory's "Laboratory Staff Competency" policy revealed "6-Month Competency: Following the Initial Competency during the first year of employment, each employee will be required to demonstrate competency in all areas of their laboratory responsibilities at 6 months of employment. Each employee must be observed for proper techniques, specimen handling and infection control as well." 2. Review of personnel records revealed a semi-annual competency assessment was not performed for the following two (2) testing personnel: Testing Personnel 8: hired February 2022; semi-annual assessment due August 2022 Testing Personnel 10: (no longer employed as of March 2023; initial training performed February 2022); semi-annual assessment due August 2022 3. In interview on July 11, 2023 at 11:40 am, the Cardiopulmonary Manager confirmed the identified testing personnel did not have semi-annual competency assessments performed.