Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1031256	07/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pam Specialty Hospital Of Tulsa	3219 S 79th East Avenue, Tulsa, OK	

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 performed on 07/19/19. The findings were reviewed with the respiratory therapy manager, chief nursing officer, director of quality manager, corporate director ancillary services, respiratory manager, and Regional Medical Laboratory laboratory support services during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the respiratory therapy manager, the laboratory failed to ensure blood collection tubes were stored as required by the manufacturer. Findings include: (1) At the beginning of the survey, the respiratory therapy manager stated the following to the surveyor: (a) Arterial Blood Gas (G3+ cartridge: pH, pCO2, pO2) testing was performed using the Abbott iSTAT analyzers (serial #326850 and serial# 312080); (b) BD Vacutainer Lithium Heparin tubes (20 tubes Lot#9036652) were used for arterial blood gas testing. (2) Later during the survey, the surveyor reviewed the manufacturer's environmental requirements for the blood collection tubes. The manufacturer's required a room temperature as follows: (a) BD Vacutainer blood collection tubes - range of 4-25 degrees C (Celsius) (3) The surveyor reviewed laboratory records from

	January 2018 through June 2019. There was no evidence that the room temperature, where the blood collection tubes were maintained, had been monitored at an acceptable range of 4-25 degrees C to accommodate the blood collection tubes; (4) The surveyor asked the respiratory therapy manager if the room temperature, where the blood collection tubes were maintained, was being monitored. The respiratory therapy manager stated the room temperature was not being monitored.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the respiratory therapy manager, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP. Findings include: (1) At the beginning of the survey, the respiratory therapy manager stated the following to the surveyor: (a) Arterial Blood Gas (G3+ cartridge: pH, pCO2, pO2) testing was performed using the Abbott iSTAT analyzers (serial #326850 and serial# 312080); (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor request the IQCP documentation from the respiratory therapy manager. The respiratory therapy manager stated the IQCP could not be located; (3) Following the onsite survey, the respiratory therapy manager provided the IQCP to the surveyor; (4) The surveyor reviewed the IQCP (dated as approved on 02/28/18) at the State Agency. The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP (Quality Control Plan) to ensure it continued to provide accurate and reliable results. There was no evidence of QA reviews since the IQCP effective date; (5) The surveyor stated to the respiratory manager, through email, there was no policy to address how the laboratory will monitor the IQCP, including the frequency of the reviews and QA reviews had been performed since the IQCP had been implemented.
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 a review of records and interview with the respiratory therapy manager, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411

	(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the respiratory therapy manager, the technical consultant failed to ensure that individuals who performed the duties and responsibilities of the technical consultant, met the qualifications for 2 of 5 proficiency testing events. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2017, 2018 and 2019 proficiency testing records; (2) The documentation verified that the attestation statements for 2 of 5 testing events had been signed by testing person #1 instead of the laboratory director/technical consultant (testing person #1 had an associates degree in science) as follows: (a) 2019 - Chemistry First Event (b) 2019 - Chemistry Second Event (3) The findings were reviewed with the respiratory, who stated the attestation statements for the above events had been signed by a person who did not qualify as a technical consultant.
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 a review of records and interview with the respiratory therapy manager, the technical consultant failed to evaluate testing persons performing moderate complexity testing at least annually. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records for 16 persons who performed moderate complexity testing during 2017, 2018 and 2019. For 1 of the 16 persons (testing person #14), there was no evidence an annual evaluation had been performed in 2018; (2) The surveyor reviewed the findings with the respiratory therapy manager. The respiratory therapy manager stated the annual evaluation had not been performed as indicated above in 2018 for the testing person.