Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1022984	05/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Kpc Promise Hospital Of Phoenix	433 E 6th St, Mesa, AZ	

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
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 lack of calibration verification documentation for blood gas testing and interview with the testing personnel, the laboratory failed to perform and document calibration verification procedures as required. Findings include: 1. The laboratory performs blood gas testing on the Gem 4000 blood gas analyzer, with an approximate annual test volume of 3,200. 2. Review of the laboratory's established policy titled, "Laboratory Quality Control for the Gem 4000 Blood Analyzer" during the survey

	conducted on May 10, 2021 stated, "PVP/Linearity studies will be run on the Gem 4000 every six months using control purchased from the Gem 4000 manufacturer." 3. No documentation was presented for review to indicate the laboratory performed a calibration verification for blood gas testing at least once every six months during 2020, 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. The laboratory performed one PVP (Performance Verification Product) test in 2020 on 7/16/20. The PVP test was not performed again until 5/05/21. 4. The facility personnel acknowledged that the PVP test was not performed every 6 months as required.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of patient test results for Blood Gas testing and interview with the facility personnel, the laboratory failed to immediately alert the individual or entity requesting the test when the test result indicates an imminently life-threatening condition, or panic or alert values. Findings include: 1. Review of blood gas test results for patient ID# 1249 performed on 02/12/20 at 12:51pm indicated two critical low test results, PCO2 = 27 mmhg and Hct = 23 mmhg. The two critical test results were each noted with two down-arrow symbols, to indicate a panic or alert value. 2. Review of blood gas test results for patient ID# 74063 performed on 08/03/19 at 08: 46am indicated a critical high test result, PCO2 = 77 mmhg. The critical test result was noted with two up-arrow symbols, to indicate a panic or alert value. 3. The laboratory's established policy titled, "Arterial Blood Gas/Chemistry Critical Values" reviewed during the survey conducted on May 10, 2021 stated, "Notify the primary or consulting physician of the critical values. Document the notification contacts on the "Critical Values Verbal Report Sticker" and place on a Physician Progress Note in the patient chart." 4. No documentation was presented for review to indicate the laboratory notified the primary or consulting physician of the critical values and documented the notification for the critical values listed above for each patient as indicated in laboratory policy. 5. The facility personnel confirmed that the critical test results referenced above were not communicated and documented per laboratory policy.
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 lack of education credentials and training documentation for testing personnel and interview with the facility personnel, (A) the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience for the type and complexity of services offered and (B) the laboratory director failed to ensure that all testing personnel receive the appropriate training for the testing performed, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. Findings include: A1. No evidence of education credentials was presented for review for four out of four testing personnel who were hired as testing personnel in December 2019, January 2020, June 2020 and September 2020. A2. The facility personnel confirmed that the laboratory failed to provide a copy of the education credentials for the four testing personnel indicated above. B1. No documentation was presented for review to indicate four out of four testing personnel referenced above received the appropriate training for blood gas testing performed on the Gem 4000 analyzer prior to testing patient specimens. B2. The facility personnel confirmed that there was no documentation of initial training for four out of four testing personnel who performed testing on the Gem 4000 analyzer.
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 lack of performance evaluation documentation and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of one testing personnel, at least semiannually during the first year the individual tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for four out of four testing personnel who began patient testing in October 2019, January 2020, September 2020 and June 2020. 2. The facility personnel confirmed that the laboratory did not have documentation of a semiannual competency evaluation for the four testing personnel indicated above.
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 lack of competency evaluation documentation for review from 2019 and 2020 and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually. Findings include: 1. During the survey conducted on May 10, 2021, no annual competency evaluation documentation from 2019 was

	presented for review for twelve out of twelve testing personnel who perform blood gas testing on the Gem 4000 analyzer. 2. No annual competency evaluation documentation from 2020 was presented for review for twelve out of twelve testing personnel who perform blood gas testing on the Gem 4000 analyzer. 3. The facility personnel confirmed that the laboratory failed to provide documentation of an annual competency evaluation from 2019 and 2020 for the testing personnel indicated above.