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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 03D1022984 | (X3) Date Survey Completed 08/29/2018 |
| Name of Provider or Supplier Kpc Promise Hospital Of Phoenix | Street Address, City, State 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 |
|---------------------------|--|
| D2009 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from 2017 and 2018 for testing performed in the specialties of Chemistry and Hematology and interview with the facility personnel, the laboratory director failed to sign the PT attestation statements. Findings include: 1. The laboratory performs Blood Gas testing in the specialties of Chemistry and Hematology, with an approximate annual test volume of 5,000. 2. The PT attestation statements presented for review for the second and third testing events of 2017 and the first and second testing events of 2018 lacked the current director's signature. 3. The PT attestation statements referenced above were signed and dated by individuals who were not listed on the CMS-209, Laboratory Personnel form presented for review during the survey. 4. The facility personnel confirmed that the PT attestation statements indicated above were not signed by the laboratory director.</p> |
| D5407 | <p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with the facility personnel, the laboratory failed to have the current laboratory director</p> |

approve, sign and date test procedures before use. Findings include: 1. The current laboratory director indicated in the CLIA Federal Database and assigned on the CMS-209, Laboratory Personnel Form presented for review during the survey has been listed as laboratory director since 7/08/2014. 2. The policy and procedure manual presented for review during the survey conducted on August 29, 2018 was not approved, signed and dated by the current laboratory director. 3. The facility personnel confirmed that the policy and procedure manual indicated above was not approved, signed and dated by the current laboratory director before use.

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 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. One out of one testing personnel was hired on May 2, 2017 to perform patient testing. 2. No evidence was presented for review to indicate a semiannual competency evaluation was performed for the testing personnel referenced above. The "Respiratory Department Laboratory Competency Assessment" form presented for review for this individual indicated the semi annual competency evaluation occurred on 7/08/16. 3. The facility personnel confirmed that the semiannual competency evaluation documentation for the testing personnel indicated above contained evaluation dates prior to this individual's date of employment.

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 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 annually after the first year the individual tested patient specimens. Findings include: 1. One out of one testing personnel was hired on May 2, 2017 to perform patient testing. 2. No evidence was presented for review to indicate an annual competency evaluation was performed for the testing personnel referenced above. The "Respiratory Department Laboratory Competency Assessment" form presented for review for this individual indicated the annual competency evaluation occurred on 01/04/17. 3. The facility personnel confirmed that the annual competency evaluation documentation for the testing personnel indicated above contained evaluation dates prior to this individual's date of employment.