

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2034890	(X3) Date Survey Completed 06/04/2018
Name of Provider or Supplier Central Prison Healthcare Complex	Street Address, City, State 1300 Western Boulevard, Raleigh, NC	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory manager on 6/4/18, the laboratory failed to discard blood collection tubes that had expired, but were available for use. Findings: During a tour of the laboratory at 4:45 p.m., the surveyor observed the following expired blood collection tubes in the phlebotomy station: 1. Red topped: a. Lot Number: 7002859, Expiration Date: 2018-05-31 - 9 tubes b. Lot Number: 6323924, Expiration Date: 2018-04-30 - 1 tube 2. Blue topped: a. Lot number: 7129980, Expiration Date: 2018-02-28 - 2 tubes 3. Gold topped: a. Lot number: 7160775, Expiration Date: 2018-05-31 - 1 tube During interview at 5:00 p.m. the laboratory manager confirmed the tubes were expired and immediately took possession of them for proper disposal.</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(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. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of laboratory procedures, review of the laboratory's 2016, 2017, and 2018 hematology, chemistry, and blood gas records, and interview with the laboratory director 6/4/18, the laboratory failed to establish and follow policies and procedures for instrument comparison studies and failed to perform comparisons twice a year to evaluate the relationship between test results for the same analyte obtained from different instruments. Findings: 1. Hematology / Blood Gas The laboratory performs hemoglobin (HGB) and hematocrit (HCT) on three analyzers: the ABL Flex Co-Ox Blood Gas Analyzer by Radiometer, the Abbott Cell-Dyn Emerald and the Abbott Cell-Dyn Ruby. Review of laboratory procedures failed to reveal a procedure defining the criteria used for evaluating comparison activities between the three analyzers for HGB and HCT. Review of the laboratory's hematology and blood gas records revealed that a biannual comparison was not performed between the three analyzers during 2016, 2017, or in 2018 prior to 6/4/18 (the date of the survey). During interview at 2:30 pm, the laboratory director confirmed that no method comparison had been performed between the three analyzers for HGB and HCT, and no procedure defining the criteria for acceptable results had been developed. 2. Chemistry / Blood Gas The laboratory performs potassium (K+), sodium (Na+) and chloride (Cl-) on three analyzers: the ABL Flex Co-Ox Blood Gas Analyzer by Radiometer, and two Architect ci400 analyzers. Review of laboratory procedures failed to reveal a procedure defining the criteria used for evaluating comparison activities between the three analyzers for potassium (K+), sodium (Na+) and chloride (Cl-). Review of the laboratory's chemistry and blood gas records revealed that a biannual comparison was not performed between the three analyzers during 2016, 2017, or in 2018 prior to 6/4/18 (the date of the survey). During interview at 2:30 pm, the laboratory director confirmed that no method comparison had been performed between the three analyzers for potassium (K+), sodium (Na+) and chloride (Cl-), and no procedure defining the criteria for acceptable results had been developed. 3. Hematology The laboratory performs complete blood cell counts on two hematology analyzers: the Abbott Cell-Dyn Emerald and the Abbott Cell-Dyn Ruby. Review of laboratory procedures failed to reveal a procedure defining the criteria used for evaluating comparison activities between the two hematology analyzers. Review of the laboratory's hematology records revealed the laboratory had performed comparisons between the two hematology analyzers on 7/5/16, 6/12/17 and 1/16/18. The hematology records failed to reveal that comparisons were performed twice a year as required. During the exit interview at approximately 5:30 pm, the laboratory director confirmed the laboratory did not have a procedure defining the criteria used for evaluating comparison activities and the laboratory had only performed comparison activities once a year on the two hematology analyzers.

D6026

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(8)

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)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions, review of a random patient test report (#0193640), and interview with staff 6/4/18, the laboratory director failed to ensure

that the laboratory's Total Prostatic Specific Antigen (TPSA) test reports included the identity of the assay used. The laboratory performed Total Prostatic Specific Antigen (TPSA) testing using the Chemiluminescence Microparticle Immunoassay "CMIA" on the Abbott Architect System analyzer. The manufacturer's product insert REF6C06, B6C060, G4-3204/R13 for this test reads in the section entitled, "WARNING: ...The results reported by the laboratory to the physicians must include the identity of the total PSA assay used...". Review of a random computer generated patient report (#0193640) revealed that the test report did not include the method used for TPSA. During interview at approximately 2:00 p.m., the laboratory director and general supervisor confirmed that the TPSA method was not included on patient test reports.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must 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 policies and procedures, review of personnel records, and interview with staff 6/4/18, the laboratory director failed to ensure that 2 of 4 testing personnel (TP #3, TP #4) were trained to perform blood gas testing and the training was documented prior to testing patient specimens. The laboratory's "Laboratory Personnel Training and Competency Review Policy" states "Upon employment, and before performing patient testing, all new personnel will be oriented to the policies and procedures of the ... Laboratory. ... Orientation and competency review documentation will be retained in the employee file for the length of their employment and for two years after employment is terminated." Review of personnel records for TP #3 and TP #4 revealed there were no training records available for review. During interview at approximately 2:45 p.m., the general supervisor stated that the personnel were trained to perform blood gas testing, but the records could not be located.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of policies and procedures, review of personnel records, and interview with staff 6/4/18, the technical supervisor (laboratory director) failed to ensure that competency evaluations were performed for 2 of 4 testing personnel (TP #3, TP #4) who perform blood gas testing. The laboratory's "Personnel Competency

Evaluation" policy states "... PROCEDURE 1. Competency assessments are performed for laboratory testing personnel by the laboratory director or designee. Competency assessments for other hospital staff performing laboratory testing are performed either by the laboratory director or by a laboratory staff member (having been found competent and designated by the laboratory director). ... 4. A Competency Review Form will be completed by the individual performing the assessment, initialed /signed by the individual being assessed to show agreement with the findings, and filed in the laboratory personnel files. All competency testing must be approved by the medical director. ... NOTES 1. All laboratory personnel are to participate in a competency assessment program for all areas in which they perform laboratory functions/duties. ..." Review of personnel records for TP #3 and TP #4 revealed there were no competency evaluations available for review for 2016, 2017, or 2018. During interview at approximately 2:45 p.m., the general supervisor stated that they used to have a blood gas supervisor who performed the competency evaluations for the blood gas staff. She stated that it had probably not been done since that supervisor left. The laboratory director confirmed at approximately 4:15 p.m. that he had not performed competency evaluations for the blood gas testing personnel.