

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0470030	(X3) Date Survey Completed 06/20/2018
Name of Provider or Supplier Purcell Municipal Hospital	Street Address, City, State 2301 N 9th Ave, Purcell, 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	The survey was performed 06/18/18 - 06/20/18. The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager, technical consultant, and CEO at the conclusion of the survey.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and the laboratory manager, the laboratory failed to maintain documentation of quality control testing for at least 2 years. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor the laboratory used the Ortho ID-MTS Gel System for patient ABO/Rh Type, Antibody Screen, and Compatibility testing; (2) On the second day of the survey, the surveyor reviewed records for the testing from 02/01 /17 through the first day of the survey and identified during 7 of the 16 months reviewed, the lot numbers of gel cards used for QC (Quality Control) testing had not been documented: (a) April 2017 (b) August 2017 (c) December 2017 (d) January 2018 (e) February 2018 (f) March 2018 (g) April 2018 (3) The surveyor reviewed the records with the technical consultant and the laboratory manager who stated to the survey the laboratory failed to include lot numbers of the gel cards used in blood bank testing as listed above: (4) The surveyor explained to the technical consultant and to the laboratory manager, the laboratory must document complete QC records, which would include lot numbers of testing materials.</p>
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the technical consultant and the laboratory manager, the laboratory failed to evaluate the accuracy of bleeding time testing at least twice annually. Findings include: (1) On the second day of the survey, the technical consultant stated to the surveyor the laboratory performed patient bleeding time testing; (2) The surveyor asked the technical consultant and the laboratory manager if the laboratory had verified the accuracy of the bleeding time testing procedure at least twice annually in 2017 and to date in 2018. The technical consultant and the laboratory manager stated to the surveyor, the laboratory had not verified bleeding time accuracy in 2017 and to date in 2018.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on a review of records, policies and procedures, and interview with the technical consultant and the laboratory manager, the laboratory failed to follow its written policy and procedure for the testing performed. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor the laboratory performed qualitative serum HCG (Human Chorionic Gonadatropin) testing using the Quidel QuickVue+ One Step test kit. In addition, the technical consultant stated to the surveyor the laboratory had established and implemented an IQCP (Individualized Quality Control Plan) to reduce the performance of external QC (Quality Control) materials from 2 levels each day of patient testing to each 30 days, and/or with a new lot number, or if a review of patient results indicates a potential problem; (2) The surveyor reviewed QC and patient records for the testing from 02/01/17 through the first day of the survey and identified the laboratory failed to follow the IQCP for the testing: (a) Test kit, Lot #703424: QC testing had not performed from 11/01/17 through 12/29/17 (b) Test kit, Lot #703628: QC testing had not been performed from 12/29/17 through 03/05/18 (c) Test kit, Lot #703751: QC testing had not been performed from 03/05/18 through 05/14/18 (3) The surveyor reviewed the findings with the technical consultant and the laboratory manager, who stated to the surveyor the laboratory failed to follow its IQCP for the performance of external QC.

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, observation of the freezer, and interview with the technical consultant and the laboratory manager, the laboratory failed to ensure materials were stored as required. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor the laboratory performed Troponin I and CKMB testing using the Alere Triage Meter Pro analyzer and testing cuvettes and used the Alere Total 5 Control materials to ensure acceptability of the test method; (2) On the third day of the survey, the surveyor observed the contents of the GE Deep Freeze in the laboratory. The surveyor identified 2 boxes of Alere Total 5 Control materials stored inside and the manufacturer's storage requirements: (a) 1 box, Level 1, Lot C3400A. The manufacturer required a storage temperature colder than or equal to -20 degrees C (Centigrade) (b) 1 box, Level 2, Lot C3403A. The manufacturer required a storage temperature colder than or equal to -20 degrees C (3) The surveyor reviewed temperature records from 12/01/17 through 05/31/18 for the GE Deep Freeze and identified the laboratory's acceptable temperature range of -15 to -20 degrees C, would allow the Alere Total 5 Control materials to be stored at temperatures warmer than the required temperature range; (4) The surveyor reviewed the findings with the technical consultant and the laboratory manager, who stated to the surveyor the laboratory's acceptable temperature limits for the GE Deep Freeze would allow storage of the Alere Total 5 Control materials warmer than the manufacturer's storage requirements.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:

Based on a review of records, observation, and interview with the technical consultant and the laboratory manager, the laboratory failed to ensure testing materials had not exceeded their expiration date. Findings include: (1) On the third day of the survey, the surveyor observed the contents of the True laboratory refrigerator. The surveyor identified a box of Synchron HDL Calibrators, Lot #M610131, expiration date 05/31/18 stored inside; (2) The surveyor showed the expired materials to the technical consultant and the laboratory manager who stated to the surveyor the expired materials were available for use and should have been discarded once they expired.