

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0470030	(X3) Date Survey Completed 06/24/2026
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 recertification survey was performed on 06/22/2026 through 06/24/2026. Standard-level deficiencies were cited.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and interim laboratory manager, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency testing program for four of four Hematology events and one of four Chemistry Core events reviewed from January 2025 through the current date. Findings include: I. HEMATOLOGY (1) A review of Hematology proficiency testing records for the period of 2025 through the current date identified the following for four of four events: (a) First 2025 Event - One of eight results had not been graded by the proficiency testing program for Educational Blood Cell Identification (sample DIF-01): (i) DIF-01 RBC Morphology (DIF) - The laboratory's reported result had not been graded by the proficiency testing program and stated, "See Data Summary" under "Expected Result". There was no evidence the laboratory reviewed the "Participant Summary Report" to evaluate their result. (b) Second 2025 Event - Two of nine results had not been graded by the proficiency testing program for Educational Blood Cell Identification (sample DIF-02): (i) DIF-02 Immature Cell (DIF) - The laboratory's reported result of 8 did not agree with the "Expected Result" of 0-2. There was no documentation to indicate corrective action had been taken for the unacceptable response; (ii) DIF-02 RBC

Morphology (DIF) - The laboratory's reported result had not been graded by the proficiency testing program and stated, "See Data Summary" under "Expected Result". There was no evidence the laboratory reviewed the "Participant Summary Report" to evaluate their result. (c) Third 2025 Event - One of one result had not been graded by the proficiency testing program and stated, "See Commentary" under "Expected Result" for Educational Blood Cell Identification (sample BCI-15): (i) BCI-15 the laboratory's reported Lymphocyte, reactive. There was no evidence the laboratory reviewed the "Participant Summary Report" to evaluate their result. (d) First 2026 Event - One of seven results had not been graded by the proficiency testing program for Educational Blood Cell Identification (sample DIF-01): (i) DIF-01 RBC Morphology (DIF) - The laboratory's reported result had not been graded by the proficiency testing program and stated, "See Data Summary" under "Expected Result". There was no evidence the laboratory reviewed the "Participant Summary Report" to evaluate their result. (2) Interview with the laboratory manager and interim laboratory manager on 06/22/2026 at 10:05 am confirmed the laboratory had not performed a self-evaluation to evaluate the non-graded results and corrective actions had not been taken as stated above. II. CHEMISTRY CORE (1) A review of Chemistry Core proficiency testing records for the period of 2025 through the current date identified the following for one of four events: (a) Second 2025 Event - Two of two results had not been graded by the proficiency testing program for Folate (sample IA-07 and IA-09): (i) IA-07 - The laboratory's reported result >20 did not agree with the "Expected result" of 3.7 - 7.1. There was no documentation to indicate corrective action had been taken for the unacceptable response. (ii) IA-09 - The laboratory's reported result 9.9 did not agree with the "Expected result" of 5.2 - 9.7. There was no documentation to indicate corrective action had been taken for the unacceptable response. (2) The records were reviewed with the laboratory manager and interim laboratory manager who stated on 06/22/2026 at 10:10 am, the laboratory had not performed a self-evaluation to evaluate the non-graded results.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

	Based on a review of records, policies and procedures and interview with the laboratory manager and interim laboratory manager, the laboratory failed to have a step-by-step written procedure for coagulation reagent lot rollover studies; and failed to have a written procedure for blood bank refrigerator alarm checks during the review period of 2025 through the current date. Findings include: I. COAGULATION REAGENT LOT ROLLOVER (1) On 06/22/2026 at 09:38 am, the laboratory manager and interim laboratory manager stated the laboratory performed Prothrombin Time/International Normalized Ratio (PT/INR) and Partial Thromboplastin Time (PTT) testing using the Werfen ACL TOP 350 analyzer; (2) A review of laboratory policies and procedures identified no evidence of a step-by-step procedure for the coagulation reagent lot rollover studies; (3) The findings were reviewed with the laboratory manager who stated on 06/24/2026 at 10:30 am, the laboratory did not have a written procedure for performing coagulation reagent lot rollover studies as stated above. II. BLOOD BANK REFRIGERATOR ALARM CHECK (1) On 06/22/2026 at 09:50 am, the laboratory interim manager stated the laboratory stored units of Packed Red Blood Cells (PRBCs) in the Sanyo blood bank refrigerator to be available for emergency patient transfusions; (2) On 06/24/2026 at 09:15 am, a review of written Blood Bank policies and procedures identified a written procedure which included the following information could not be located: (a) Step by step instructions for performing alarm checks; (b) The frequency at which alarm checks were to be performed; (c) Process for documentation and acceptability of the alarm check results. (3) The findings were reviewed with the laboratory manager who stated on 06/24/2026 at 09:30 am, a procedure which included the items above was not available.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and interim laboratory manager, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Alcor miniiSED Erythrocyte Sedimentation Rate (ESR) analyzer during the review period of January 2026 through the current date. Findings include: (1) On 06/22/2026 at 09:27 am, the laboratory manager and interim laboratory manager stated the laboratory performed ESR testing using the Alcor Scientific MiniiSED analyzer; (2) A review of the Operator's Manual in Section 15.1 "Deep Clean Procedure" stated, "The frequency for Deep Cleaning is monthly or every 1000 samples run, whichever comes first"; (3) A review of maintenance logs from January 2026 through the current date identified the maintenance had not been documented as performed prior to 03/28/2026; (4) The records were reviewed with the laboratory manager who stated on 06/23/2026 at 11:01 am, the maintenance procedures had not been documented as performed as stated above.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory manager and interim laboratory manager, the laboratory failed to perform at least two levels of quality control (QC) materials for one of sixty-two days of patient Erythrocyte Sedimentation Rate (ESR) testing reviewed from January through May 2026. Findings include: (1) On 06/22/2026 at 09:27 am, the laboratory manager and interim laboratory manager stated the laboratory performed ESR testing using the Alcor Scientific MiniiSED analyzer; (2) A review of QC and patient testing records from January through May 2026 identified at least two levels of QC materials had not been performed each day of ESR testing reviewed for one of sixty-two days of patient testing; (3) The records were reviewed with the laboratory manager and interim laboratory manager who stated on 06/22/2026 at 03:00 pm, two levels of QC materials had not been performed each day of patient testing as stated above.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory manager and interim laboratory manager, the laboratory failed to perform positive and negative control materials for two of 26 days of patient serum pregnancy testing reviewed between January through May 2026; six of ten days of Serum Mononucleosis testing reviewed between January through May 2026; and six of sixty days of urine drug screen testing reviewed between March through May 2026. Findings include: I. SERUM PREGNANCY (1) On 06/22/2026 at 10:20 am, the laboratory manager and interim laboratory manager stated the laboratory performed Qualitative Serum Pregnancy testing using the Cardinal Health hCG Combo Rapid test kits on serum samples; (2) A review of Quality Control (QC) and patient testing records for testing performed between January and May 2026 identified positive and negative QC materials had not been performed each day of patient testing for two of twenty-six days (the specific dates were 04/09/2026 and 04/13/2026); (3) The records were reviewed with the laboratory manager and interim laboratory manager who stated on 06/22/2026 at 03:05 pm, QC materials had not been performed each day of patient testing. II. OSOM - MONO TEST (1) On 06/22/2026 at 10:25 am, the laboratory manager stated the laboratory performed Mononucleosis testing using the Sekisui Diagnostics - OSOM Mono test kit on serum and plasma samples; (2) A review of QC and patient testing records for testing performed between January and May 2026 identified positive and negative QC materials had not been performed each day of patient testing for six of ten days (the specific dates were 01/08/2026, 01/22/2026, 01/26/2026, 03/13/2026, 03/25/2026, and 05/27/2026); (3) The records were reviewed with the laboratory manager and interim laboratory manager who stated on 06/22/2026 at 03:00 am, QC materials had not been performed each day of patient testing. III. BIORAD TOX-SEE URINE DRUG SCREEN (1) On 06/22/2026 at 10:50 am, the laboratory manager and interim laboratory manager stated the laboratory performed Drug Screen testing using the BioRad Tox/See Drug Screen Test kit on urine samples; (2) A review of QC and patient testing records for testing performed between March through May 2026 identified positive and negative QC materials had not been performed each day of patient testing for six of sixty days (the specific dates were 03/09/2026, 03/20/2026, 04/10/2026, 04/18/2026, 04/29/2026, and 05/08/2026); (3) The records were reviewed

with the laboratory manager and interim laboratory manager who stated on 06/22 /2026 at 03:10 pm, QC materials had not been performed each day of patient testing.