

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0475880	(X3) Date Survey Completed 06/14/2025
Name of Provider or Supplier Holdenville General Hospital	Street Address, City, State 100 Mcdougal Drive, Holdenville, 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 06/10,11,12,13/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with technical consultant #2, laboratory manager, and testing person #2 at the conclusion of the survey.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with the laboratory manager, the laboratory failed to follow manufacturer's directions to ensure Nova StatStrip glucose test strips had not exceeded their room temperature expiration date; and failed to follow manufacturer's directions for ensuring Fentanyl testing cassettes were not compromised prior to patient testing. Findings include: I. NOVA STATSTRIPS (1) On 06/10/2025 at 12:28 pm, the laboratory manager stated glucose testing was performed on the Nova Stat Meter in the emergency department and on the nursing floor; (2) Observation of the emergency department on 06/10/2025 at 12:28 pm identified one open bottle (Lot #0325027249, expiration 01/27/2027) of Novostat test strips stored at room temperature, without documentation of when they were put in use; (3) Review of the manufacturer's storage requirements stated the following: (a) "Write the discard date on the bottle label. The test strips are stable for six months after opening or until the expiration date on the bottle label, whichever comes first". (4) Interview with the laboratory manager on 06/10/2025 at 12:28 pm confirmed the bottle had been opened without a method to monitor if they exceeded the manufacturer's modified expiration date. II. FENTANYL RAPID TEST CASSETTES (1) On 06/10/2025 at 12:38 pm, the laboratory manager stated Fentanyl testing was</p>

performed using Discover Fentanyl Rapid Test Cassettes; (2) Observation of the laboratory on 06/10/2025 at 12:38 pm identified one open cassette (Lot #FYL23110008U, expiration 11/23/2025) without documentation of when it was opened, stored in a biohazard bag; (3) Review of the manufacturer's warnings and precautions stated the following: (a) "Do not use the test if foil pouch is torn or damaged, The test device should remain in the sealed pouch until use". (4) Interview with the laboratory manager on 06/10/2025 at 12:38 pm confirmed the cassette had not been kept inside the sealed pouch until ready for use.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

(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 policies and procedures, interview with the laboratory manager and technical consultant #2, the laboratory failed to have a written procedure that explained the current practice and procedure being performed in the laboratory for processing specimens for Chemistry and Immunoassay testing using two of two centrifuges; and failed to follow their policy for ensuring the health status of the donors for the Coagulation lot rollover studies. Findings include: I. CHEMISTRY AND IMMUNOASSAY (1) On 06/10/2025 at 11:00 am, the laboratory manager stated the following: (a) Routine Chemistry and Immunoassay testing were performed using the Siemens Dimension EXL 200 analyzer; (b) The specimens were processed using the Silencer #67943 centrifuge at a speed of 4000 rpm (revolutions per minute) for five minutes, and the Benchtop 6F centrifuge at a speed of 3365 rpm for eight minutes. (2) A review of the procedure titled, "Platelet Poor Plasma and Serum" identified the following: (a) Under the heading "Clinical Application" it stated, "It is also necessary for all chemistry and immunoassay plasma and/or serum samples to be platelet poor per the laboratory best practices"; (b) Under the heading "Specimen Collection and Handling" it stated, "Specimens will be evaluated on the appropriate centrifuges annually"; (c) Under the heading "Procedure" it stated, "Each tube will be centrifuged for the appropriate time in the appropriate centrifuge. For example, a Li heparin tube for chemistry will be centrifuged in the Silencer #67943 for 5 minutes at 4000 rpms and The Benchtop 6F centrifuge for 8 minutes at 3365 rpms. A platelet count will then be performed before testing on that tube to ensure platelet poor plasma". (3) Interview with technical consultant #2 during a phone call following the survey on 06/17/2025 at 11:25 am confirmed the laboratory did not perform platelet poor plasma using Lithium Heparin tubes and the procedure did not reflect the laboratory's current practice for the two centrifuges. II. NORMAL PATIENTS FOR PT/PTT LOT ROLLOVER (1) On 06/10/2025 at 11:00 am, the laboratory manager stated the following: (a) The laboratory performed Coagulation (PT/INR and PTT) testing using the ACL Elite analyzer; (b) During the coagulation lot rollover studies, the laboratory utilized ten healthy adult males and ten healthy adult female donors. (2) A review of the procedure titled, "Protime and PTT Lot Roll-Over Procedures" identified the following: (a) Under the heading "Normal Reference Range" section b, it stated, "Need at least 20 patients for a rollover-use the questionnaire; it needs to include age, gender, name or identifier, healthy patients (status= no pathological conditions like diabetes, lupus, auto-immune disease, nothing affecting coagulation);

(3) A review of the "Hemostasis Roll-Over Normal Patient Worksheet" identified no documentation to verify the health status of the donors; (4) Interview with technical consultant #2 and the laboratory manager on 06/12/2025 at 02:55 pm confirmed the laboratory failed to include questionnaires for ensuring the health status of the donors for the coagulation lot rollover studies. 48517 Based on review of policy, direct observation, and interview with technical consultant #2, the laboratory failed to follow their policy for blood bank specimen labeling for two of two patients observed. Findings include: 1. On 06/11/2025 at 1:00 pm a review of the procedure, "Specimen Identification and Integrity" stated, "All samples must be labeled with the patient's first and last names, patient's date of birth, date and time of collection, and the phlebotomist's initials."; 2. Direct observation of the lab on 06/11/2025 at 1:00 pm, revealed two Ortho MTS blood bank gel testing cards labeled with a patient's first and last name only; 3. Interview with technical consultant #2 at 1:00 pm on 06/11/2025, confirmed the laboratory failed to follow their policy for specimen identification and integrity.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on a review of laboratory procedures and interview with technical consultant #2 and laboratory manager, the laboratory failed to ensure one of six procedures had been approved, signed, and dated by the laboratory director. Findings include: (1) A review of laboratory procedures identified no evidence the procedure titled "Platelet Poor Plasma and Serum" had been signed and dated as approved by the laboratory director; (2) The procedure was reviewed with technical consultant #2 and laboratory manager. Both stated on 06/13/2025 at 09:30 am, the procedure had not been signed and dated as approved by the laboratory director.

D5413

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

(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 observation and interview with technical consultant #2, the laboratory failed to ensure three of three types of blood collection tubes were stored as required by the manufacturer at the emergency room nurse's station. Findings include: (1) Observation of the emergency room nurse's station and interview with technical consultant #2 on 06/11/2025 at 2:00 pm, identified the following: (a) Eight Vacuette Gel and Lithium Heparin tubes, lot # B241134X, storage temperature of 4-25 degrees

(C) centigrade; (b) Ten Vacuette K2 EDTA 7.2 mg tubes, lot # B241134W, storage temperature of 4-25 degrees C; (c) Seven Vacuette Sodium Citrate Collection tubes, lot # B240833V, storage temperature of 4-25 degrees C. (2) Interview with technical consultant #2 on 06/11/2025 at 02:00 pm confirmed the laboratory was not monitoring the temperature of the emergency room nurse's station.

D5435

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(2)

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with technical consultant #2 and the laboratory manager, the laboratory failed to have a written function check protocol to ensure urine and coagulation centrifuges were functioning properly during the review period of June 2023 through the current date. Findings include: I. URINE CENTRIFUGE (1) On 06/10/2025 at 10:19 am, technical consultant #2 and the laboratory manager stated the following: (a) The laboratory performed urine sediment examinations; (b) The urine specimens were processed at a speed of 1800 rpms (revolutions per minute) for 5 minutes using the Drucker Diagnostics Horizon 642 VES centrifuge. (2) Although the speed and time function checks had been performed at least twice annually for the urine centrifuge, a function check protocol that defined the frequency of the speed and timer checks and limits of acceptability could not be located; (3) The findings were reviewed with technical consultant #2 and the laboratory manager who confirmed on 06/11/2025 at 02:30 pm, there was no written protocol that defined the centrifuge speed and timer function check. COAGULATION CENTRIFUGE (1) On 06/10/2025 at 10:19 am, technical consultant #2 and the laboratory manager stated the following: (a) The laboratory performed PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing using the ACL Elite analyzer; (b) The specimens were processed using the Hamilton Bell Vanguard V6500 centrifuge at a speed of 3600 rpm for 15 minutes. (2) Although the speed and time function checks had been performed annually for the centrifuge, a function check protocol that defined the frequency of the speed and timer checks and limits of acceptability could not be located; (3) The findings were reviewed with technical consultant #2 and laboratory manager who confirmed on 06/11/2025 at 02:30 pm, there was no written protocol that defined the centrifuge speed and timer function check.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

(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 a review of records and interview with technical consultant #2, the laboratory failed to perform calibration verification procedures at least once every six months for the Triage D-Dimer test system during the review period of 12/29/2023 through the current date. Findings include: (1) On 06/12/2025 at 10:45 am, technical consultant #2 stated the laboratory performed D-Dimer testing using the Triage meter pro analyzer; (2) A review of records from 12/29/2023 through the current date identified no evidence the calibration verification procedures had been performed for D-dimer between 06/12/2024 and 05/22/2025. (3) The findings were reviewed with technical consultant #2, who stated on 06/12/2025 at 10:45 am, the calibration verification procedures had not been performed every six months as stated above.

D5553

IMMUNOHEMATOLOGY

CFR(s): 493.1271(b)(f)

(b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b).

This STANDARD is not met as evidenced by:

Based on a review of records, written policy, and interview with technical consultant #2, the laboratory failed to comply with 21 CFR 606.160(b)(3)(v). The laboratory failed to ensure that emergency release of blood forms had been signed by the physician for six of 13 emergency releases reviewed. Findings include: (1) On 06/12/2025 at 10:00 am, technical consultant #2 stated the laboratory maintained units of (PRBC's) packed red blood cells. The units were to be used for patient transfusions; (2) On 06/12/2025 a review of the form titled, "Emergency transfusion request for uncrossmatched blood or for universal donor blood" required a Release of Uncrossmatched form be completed and stated, "I believe the life of this patient _____ will be in jeopardy without an emergency transfusion. I therefore accept responsibility for any adverse reactions, which may occur from this transfusion."; (3) A review of documentation of emergency issues identified the following for six of 13 patient records: (a) Three units of O negative packed red blood cells had been released to a patient on 04/20/2025. The "Release of Uncrossmatched Blood" form appeared to be signed by a mid-level provider and not a physician; (b) One unit of O negative packed red blood cells had been released to a patient on 07/16/2024. The "Release of Uncrossmatched Blood" form appeared to be signed by a mid-level provider and not a physician; (c) Two units of O negative packed red blood cells had been released to a patient on 07/04/2024. The "Release of Uncrossmatched Blood" form appeared to be signed by a mid-level provider and not a physician; (d) One unit of O negative packed

red blood cells had been released to a patient on 06/21/2024. The "Release of Uncrossmatched Blood" form appeared to be signed by a mid-level provider and not a physician; (e) Two units of O negative packed red blood cells had been released to a patient on 06/24/2024. The "Release of Uncrossmatched Blood" form appeared to be signed by a mid-level provider and not a physician; (f) One unit of O Positive packed red blood cells had been released to a patient on 07/14/2024. The "Release of Uncrossmatched Blood" form appeared to be signed by a mid-level provider and not a physician; (4) The documentation was reviewed with technical consultant #2, who stated on 06/12/2025 at 10:00 am, the emergency releases had not been signed by a physician.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a review of records and interview with technical consultant #2, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for three of 20 proficiency testing events reviewed in 2024 and 2025. Findings include: (1) On 06/10/2025, a review of 2024 and 2025 proficiency testing events identified attestation statements had not been signed before the graded evaluation was completed by the proficiency testing program for three of 20 events reviewed: (a) First Chemistry Miscellaneous Event 2025 - The graded evaluation was completed on 05/30/2025 and the attestation statement had not been signed by the laboratory director; (b) Second Hematology/Coagulation Event 2024 - The grade evaluation was completed on 09/16/2024 and the attestation was signed 09/16/2024; (c) Second Chemistry Core Event 2024 - The graded evaluation was completed on 07/22/2024 and the attestation was signed on 07/22/2024. (2) The records were reviewed with technical consultant #2, who stated on 06/10/2025 at 01:10 pm the attestation statements had not been signed timely as stated above.