

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0050874	(X3) Date Survey Completed 07/30/2025
Name of Provider or Supplier Osu University Health Services	Street Address, City, State 1202 West Farm Road, Stillwater, 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 07/29,30/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the facility director, associate director of clinical operations, laboratory director, and testing person #1 during an exit conference performed 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 and testing person #1, the laboratory failed to follow manufacturer's directions to ensure True Metrix Pro glucose test strips had not exceeded their room temperature expiration dates. Findings include: (1) On 07/29/2025 at 12:30 pm, the laboratory manager stated glucose testing was performed on the Tru Metrix Pro; (2) Observation of the laboratory on 07/29/2025 at 12:30 pm identified one open bottle (Lot #, Z65992S expiration 08/31/2026) of Tru Metrix Pro 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 date first opened on bottle. Discard bottle after expiration date printed on the bottle". (4) Interview with the laboratory manager and testing person #1 on 07/29/2025 at 12:30 pm confirmed the bottle had been opened without a method to monitor if they exceeded the manufacturer's modified expiration date.</p>
D6016	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p>

(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 the laboratory manager, 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 19 proficiency testing events reviewed in 2024 and 2025. Findings include: (1) On 07/29/2025, a review of 2024 and 2025 proficiency testing events identified attestation statements had been signed after the graded evaluations were completed by the proficiency testing program for three of 19 events reviewed: (a) First event 2024 Immunology - The graded evaluation was completed on 04/25/2024 and the attestation statement had not been signed by the laboratory director until 05/01/2025; (b) Second event 2024 Immunology - The graded evaluation was completed on 08/29/2024 and the attestation statement had not been signed by the laboratory director until 09/06/2024; (c) First event 2024 Hematology/Coagulation - The graded evaluation was completed on 04/16/2024 and the attestation statement had not been signed by the laboratory director until 05/01/2024; (2) The records were reviewed with the laboratory director who stated on 07/29/2025 at 02:00 pm the attestation statements had not been signed timely as stated above.