

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D0670093	<b>(X3) Date Survey Completed</b> 11/19/2025
<b>Name of Provider or Supplier</b> Utica Park Clinic - Owasso	<b>Street Address, City, State</b> 10512 N 110th East Ave, Suite 300, Owasso, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The recertification survey was performed on 11/19/2025. The laboratory was found in compliance with standard-level deficiencies cited.
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant, the laboratory failed to label two of two bins of BD butterfly blood collection devices with the expiration date, and lot number of the contents. Findings include: (1) On 11/19/2025 at 11:35 am, observation of the laboratory identified two unlabeled bins containing the following items; (a) Approximately 50 BD 23 gauge butterfly blood collection devices that had been removed from their primary packaging and placed into the bin; (b) Approximately 50 BD 21 gauge butterfly blood collection devices that had been removed from their primary packaging and placed into the bin. (3) Interview with the technical consultant on 11/19/2025 at 11:35 am, confirmed that the packaging had been discarded and they had no way to track the lot numbers or expiration dates of the butterfly collection devices; (4) The findings were reviewed with the technical consultant on 11/19/2025 at 11:35 am who stated the bins had not been labeled with the contents, expiration date, and lot numbers.</p>
<b>D5807</b>	<p>TEST REPORT CFR(s): 493.1291(d)</p>

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the technical consultant, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population for two of two patient reports reviewed. Findings include: (1) On 11/19/2025 at 1:00 pm, the technical consultant stated the laboratory performed CBC (Complete Blood Count) testing using the Medonic M-series hematology analyzer; (2) Review of two patient CBC reports (the first report was for an adult female patient with the testing performed on 11/18/2025 at 01:55 pm and the second report was for an adult male patient with the testing performed on 03/17/2025 at 01:10 pm) identified both reports included the same reference intervals for the following CBC parameters: (a) WBC (White Blood Cell) count - 3.5-10.0 ( $10^3/\text{mL}$ ); (b) RBC (Red Blood Cell) count - 3.5-5.5 ( $10^6/\text{mL}$ ); (c) Hemoglobin - 11.5-16.5 g/dL; (d) Hematocrit - 35.0-55.0 %; (e) Platelets - 100-400 ( $10^3/\text{mL}$ ). (3) The reports were reviewed with the technical supervisor who stated on 11/19/2025 at 01:00 pm, the patient reports did not include gender specific reference ranges for WBC, RBC, Hemoglobin, Hematocrit, and Platelets.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the technical consultant, the laboratory failed to ensure competency evaluations for moderate complexity testing had been performed at least two times (semiannually) during the first year of testing for one of one testing person. Findings include: (1) On 11/19/2025, a review of personnel records for one of one person performing moderate complexity testing identified the following: (a) Testing Person #3 - The initial training was completed on 08/22/2024 and the first competency evaluation was completed on 03/18/2025. The second competency evaluation was not performed until 11/17/2025; (2) Interview with the technical consultant on 11/19/2025 at 12:30 pm confirmed that the second competency evaluation had not been completed during the first year of patient testing.