Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0670093	02/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Utica Park Clinic - Owasso	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The recertification survey was performed on 02/06/2024 The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant at the conclusion of the survey.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (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. (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, policies and procedures, and interview with the technical consultant, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly for one of two annual function checks performed during the review period of January 2022 through the current date. Finding include: (1) On 02/06/2024 at 2:00 pm, the technical consultant stated the following: (a) Urine sediment examinations were performed by the laboratory; (b) The specimens were processed a Unico centrifuge at a speed of 2000 rpm (revolutions per minute) +/- 250 RPM for 5 minutes; (2) A review of the procedure titled, " Laboratory centrifuge maintenance", stated "Centrifuge RPM verification shall be performed and recorded at least once per year. RPM for urine centrifuges must be 2000+/- 250" for five minutes +/- 30 seconds"; (3) A review of centrifuge function check records during 2022 through the current date identified on 12/5/2023 the centrifuge speed timer had been checked at eight minutes, rather than five minutes; (5) The records

	were reviewed with the technical consultant, who stated on 02/06/2024 at 2:00 pm, the laboratory had not followed their policy.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory director or designee failed to ensure proficiency testing reports were appropriately reviewed for five of six Hematology events reviewed in 2022 and 2023. Findings include: (1) A review of 2022 and 2023 Hematology proficiency testing (PT) events identified the "Performance Evaluations" included a space for the laboratory director or designee signature and date (indicating review of the graded evaluation). The following was identified for five of six events: (a) API First PT event of 2022 - The Performance Evaluation had not been signed and dated until 01/18/2024 as reviewed by the laboratory director or designee; (b) API Second PT event of 2022 - The Performance Evaluation had not been signed and dated until 01/18/2024 as reviewed by the laboratory director or designee; (c) API Third PT event of 2022 - The Performance Evaluation had not been signed and dated until 01/18/2024 as reviewed by the laboratory director or designee; (d) API First PT event of 2023 - The Performance Evaluation had not been signed and dated until 01/18/2024 as reviewed by the laboratory director or designee; (e) API First PT event of 2023 - The Performance Evaluation had not been signed and dated until 01/18/2024 as reviewed by the laboratory director or designee. (2) The records were reviewed with the technical consultant who stated on 02/06/2024 at 1:00 pm, the graded evaluations, as indicated above, had not been signed and dated as reviewed by the laboratory director or designee until 01/18/2024.