Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0857440	03/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Black Hawk Health Center	356110 E 930 Road, Stroud, 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 03/20/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and laboratory manager at the conclusion of the survey.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and laboratory manager, the laboratory failed to utilize the demonstrated reportable ranges for two of five analytes reviewed on the Ortho Vitros XT 3400 analyzer put into use in December 2021. Findings include: (1) On 03/20/2024 at 10:45 am, the laboratory manager stated the laboratory began using the Ortho Vitros XT 3400 analyzer to perform routine chemistry testing, which included the analytes Cholesterol and CK (Creatine Kinase), in December 2021; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) Cholesterol - 47.2-417.2 mg/dL (b) CK - 48.7-1671.4 U/L (3) Interview with the laboratory manager and laboratory director on 03/20/2024 at 02:00 pm, confirmed the laboratory was using the following reportable ranges instead of those that had been demonstrated by the laboratory: (a) Cholesterol - 0-90000000 mg/dL (b) CK - 0-1600 U/L

D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that 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 director, 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 five of 13 proficiency testing events reviewed in 2022 and 2023. Findings include: (1) A review of 2022 and 2023 proficiency testing events identified attestation statements had been signed up to three months after the samples had been tested for five of 13 events reviewed: (a) First Hematology Event 2022 - The sample testing had been completed on 03/30/2022 and the attestation statement had not been signed by the previous laboratory director until 06/24/2022; (b) First Chemistry Core Event 2022 - The sample testing had been completed on 02/01/2022 and the attestation statement had not been signed by the previous laboratory director until 03/18/2022; (c) Second Hematology Event 2022 - The sample testing had been completed on 08/03/2022 and the attestation statement had not been signed by the previous laboratory director until 09/16/2022; (d) First Chemistry Core Event 2023 - The sample testing had been completed on 01/27/2023 and the attestation statement had not been signed by the previous laboratory director until 04/07/2023; (e) Second Chemistry Core Event 2023 - The sample testing had been completed on 06/02/2023 and the attestation statement had not been signed until the current laboratory director (hired in August 2023) signed it on 08/30/2023. (2) The records were reviewed with the laboratory director who stated on 03/20/2024 at 02:00 pm the attestation statements had not been signed timely as stated above.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and laboratory manager, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for two of two persons during the review period of December 2021 through the current date. Findings include: (1) A review of personnel records for two persons performing moderate complexity testing from December 2021 through the current date identified no evidence annual competency evaluations had been performed for two of two persons as follows: (a) Laboratory Manager - Not performed until 10/30/2023 (b) Testing Person #2 - Not

	performed until 10/30/2023 (2) The records were reviewed with the laboratory director and laboratory manager. Both stated on 03/20/2024 at 10:50 am, the annual evaluations had not been performed.