Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0857440	12/01/2021
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 12/01/2021. The findings were reviewed with the laboratory manager at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 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. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to following the manufacturer's instructions for specimen transport and storage for 1 of 3 patient specimens. Findings include: (1) On 12/01/2021 at 09:45 am, the laboratory manager stated the following to the surveyor: (a) The laboratory performed COVID-19 testing using the following instrument (i) Abbott BinaxNOW COVID-19 Ag Card - qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal swabs. (2) The surveyor reviewed the manufacturer's product insert titled, "BinaxNOW COVID-19 Ag" which stated, "For best performance, direct nasal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15-30C) for up to one (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than one (1) hour delay occurs, dispose of sample. A new sample must be collected for testing."; (3) The surveyor reviewed 3 test reports for patients tested on 04/14/2021, 08/26/2021, and 12/01/2021 and identified the following: (a) Patient Report #1 - Specimen collection date and time (04/14/2021 at 09:55 am) and the

	result date and time (04/14/2021 at 09:55 am); (4) The surveyor was not able to determine if the results had been interpreted within the one (1) hour after collection since the time between the specimen collection date and time and the result date and time were identical; (5) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated on 12/01/2021 at 12:05 pm the laboratory could not prove the results had been interpreted within one (1) hour after collection as indicated above.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in 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 failed to review and evaluate proficiency testing results for 2 of 20 events. Findings include: (1) On 12/01/2021, the surveyor reviewed 2020 and 2021 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) First 2021 Chemistry Core Event (i) Cholesterol HDL (High Density Lipoprotein) - 3 of 5 results exhibited a positive bias (aa) Sample CH-06 - SDI of 2.7 (bb) Sample CH-07 - SDI of 3.6 (cc) Sample CH-08 - SDI of 2.0 (b) Third 2021 Chemistry Core Event (i) Total Cholesterol - 3 of 5 results exhibited a positive bias (aa) Sample CH-11 - SDI of 2.0 (bb) Sample CH-12 - SDI of 2.4 (cc) Sample CH-15 - SDI of 2.7 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory manager. The laboratory manager stated on 12/01/2021 at 11:30 am the biases had not been addressed.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for 2 of 3 Chemistry Miscellaneous events reviewed. Findings include: (1) On 12/01/2021, the surveyor reviewed proficiency testing records for the first and second events in 2020 and the first event of 2021. The following was identified for 2 of 3 Chemistry Miscellaneous events: (a) First 2020 Chemistry Miscellaneous Event for Microalbumin - 1 of 3 results had not been graded by the proficiency testing program: (i) For 1 of 3 results (MA-01), the following was identified: (aa) MA-01 - Under "Expected Results" it stated, "See Data Summary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (b) Second 2020 Chemistry

	Miscellaneous Event for Microalbumin - 1 of 3 results had not been graded by the proficiency testing program: (i) For 1 of 3 results (MA-05), the following was identified: (aa) MA-05 - Under "Expected Results" it stated, "See Data Summary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (2) The surveyor reviewed the records with the laboratory manager who stated on 12/01/2021 at 11:25 am, the laboratory had not evaluated the results that were not graded by the proficiency testing program and corrective action had not been taken as indicated.
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, written policy and procedures and interview with the laboratory manager, the laboratory failed to follow their function check protocol for ensuring the urine centrifuge was functioning properly for two of two function checks. Findings include: (1) On 12/01/2021 at 09:35 am, the laboratory manager stated the following to the surveyor: (a) The laboratory performed microscopic urine sediment analysis; (i) The specimens were processed in the Ultra 8 V (serial number V127586) centrifuge at a speed of 1800 rpm (Revolutions Per Minute) and a time of 5 minutes; (2) The surveyor asked the laboratory manager to explain how often function checks (speed and timer checks) were performed on the centrifuge. The laboratory manager stated on 12/01/2021 at 11:00 am it was the laboratory's policy to check the speed and timer of the centrifuge annually; (3) The surveyor reviewed the laboratory's written policies and procedures titled, "LABORATORY POLICY AND PROCEDURE MANUAL" the written procedure titled, "Equipment Maintenance" under the section titled, " A. Urine Centrifuge" stated, "The urine centrifuge is checked by the Indian Health (IHS) Service Biomed Technician annually for speed of 1800 rpm +/-5% and time of 5 minutes +/- 10 seconds acceptable range(s)."; (4) The surveyor reviewed the centrifuge function check records that had been performed in 2020 and 2021. The centrifuge time had been checked as follows: (a) Ultra 8 V urine centrifuge (i) 08/21 /2020 for three minutes (ii) 10/22/2021 for two minutes (5) The surveyor reviewed the records with the laboratory manger and asked if the timer had been checked at a time of 5 minutes according to the laboratory's policy for performing microscopic urine sediment analysis. The laboratory manager stated on 12/01/2021 at 11:55 am, the timer had not be checked at 5 minutes as indicated above.