

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0857440	(X3) Date Survey Completed 01/07/2026
Name of Provider or Supplier Black Hawk Health Center	Street Address, City, State 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 01/06,07/2026. The laboratory was found in compliance with standard-level deficiencies cited.
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 director, the laboratory failed to follow manufacturer's directions to ensure Siemens DCA Vantage hemoglobin A1C cartridges had not exceeded their room temperature expiration data for nine of nine cartridge type observed. Findings include: (1) On 01/06/2026 at 11:28 am, the laboratory director stated hemoglobin A1C testing was performed on the Siemens DCA Vantage analyzer; (2) Observation of the laboratory on 01/06/2026 at 11:30 am identified nine hemoglobin A1C cartridges (Lot #0861) stored at room temperature, without documentation of when they were removed from refrigeration; (3) Review of the manufacturer's storage requirements showed the following: (a) The cartridges were stable at 2-8 degrees C (Centigrade) until the expiration date listed on the box; (b) The cartridges were stable at room temperature (18-30 degrees C) for 90 days. (4) Interview with the laboratory director on 01/06/2026 at 11:45 am confirmed the cartridges had been placed at room temperature without a method to monitor if they exceeded the manufacturer's room temperature expiration date.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p>

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on a review of the policy and procedure manual and interview with the laboratory director and laboratory manager, the laboratory failed to have complete written policies and procedures for two of two test systems reviewed. Findings include: I. SYSMEX XN-430 (1) On 01/06/2026 at 11:00 am, the laboratory manager stated the laboratory performed CBC (Complete Blood Count) testing using the Sysmex XN-430 analyzer; (2) On 01/07/2026, a review of the laboratory policy and procedure manual for the Sysmex XN-430 identified no evidence of the following: (a) Step-by-step instructions for the test procedure; (b) Quality Control procedures that include: (i) Type of control (e.g., manufacturer or in-house, electronic); (ii) Identity (e.g., normal, abnormal, level I, II, etc.); (iii) Number and frequency of testing controls; (iv) Quality control limits; (v) Criteria to determine acceptable control results. (c) Procedure explaining the corrective actions for unacceptable controls or calibration results; (d) Limitations in the test methodology; (e) Reference intervals; (f) Panic values; (g) Reportable ranges (3) The manual was reviewed with the laboratory director and laboratory manager who stated on 01/07/2026 at 11:10 am, the manual did not include the complete procedures for the CBC testing as stated above. II. ORTHO VITROS 3400 (1) On 01/06/2026 AT 11:05 am, the laboratory manager stated the following: (a) The laboratory performed CMP (Comprehensive Metabolic Panel), Lipid, CK (Creatine Kinase), and Direct Bilirubin testing using the Ortho Vitros 3400 analyzer; (2) On 01/07/2026, a review of laboratory policies and procedures for the Ortho Vitros 3400 test system identified no evidence for the following: (a) Step-by-step instructions for the test procedure; (b) Quality Control procedures that include: (i) Type of control (e.g., manufacturer or in-house, electronic); (ii) Identity (e.g., normal, abnormal, level I, II, etc.); (iii) Number and frequency of testing controls; (iv) Quality control limits; (v) Criteria to determine acceptable control results. (c) Procedure explaining the corrective actions for unacceptable controls or calibration results; (d) Limitations in the test methodology; (e) Imminently life-threatening test results, or panic or alert values. (3) The findings were reviewed with the laboratory director and laboratory manager who stated on 01/07/2026 at 11:30 am, the chemistry procedures did not include all of the required information.