

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2120433	(X3) Date Survey Completed 10/25/2019
Name of Provider or Supplier Healthcare Express-Choctaw	Street Address, City, State 14321 Ne 23rd St, Choctaw, 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 10/25/19. The findings were reviewed with the technical consultant and testing person #1 at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and testing person #1, the laboratory failed to have a policy to verify the stated value of control materials before they were put into use. Findings include: (1) At the beginning of the survey, testing person #1 stated the following to the surveyor: (a) The laboratory used</p>

the Sysmex XP-300 analyzer to perform CBC (Complete Blood Count) testing; (b) Three levels of Sysmex EightCheck-3WP control materials were analyzed each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) Later during the survey, the surveyor reviewed written policies and procedures. A procedure to verify the stated value of control materials could not be located. (3) The surveyor asked the technical consultant and testing person #1 if a written procedure to verify the manufacturer's stated value of control materials existed. The technical consultant and testing person #1 stated a procedure had not been written.