Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0670493	11/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Stillwater Medical Physician Clinic Laboratory	1815 West 6th Street, Stillwater, 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	A recertification survey was performed on 11/06/19. The findings were reviewed with the laboratory manager, administrative laboratory director, clinic laboratory supervisor, and microbiology supervisor during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
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 clinic laboratory supervisor, the laboratory failed to review and evaluate proficiency testing results for 5 of 16 events. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records and identified the following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Third 2018 Chemistry Core Event (i) Chloride - 4 of 5 results exhibited a negative bias (aa) CM-11- SDI of -2.7 (bb) CM-12 - SDI of -2.9 (cc) CM-13 - SDI of -2.1 (dd) CM-14 - SDI of -2.9 (ii) Potassium - 5 of 5 results exhibited a negative bias (aa) CM-11- SDI of -2.2 (bb) CM-12 - SDI of -2.9 (cc) CM-13 - SDI of -2.4 (dd) CM-14 - SDI of -3.5 (ee) CM-15 - SDI of -2.6 (b) First 2018 Hematology Event (i) MPV (Mean Platelet Volume) - 3 of 5 results exhibited a negative bias (aa) HEM-02 - SDI of -2.1 (bb) HEM-03 - SDI of -2.0 (cc) HEM-04 - SDI of -2.0 (c) Second 2018 Hematology Event (i) Platelet - 3 of 5 results exhibited a positive bias (aa) HEM-07 - SDI of 2.5 (bb) HEM-08 - SDI of 2.0 (cc) HEM-09 - SDI of 2.7 (d) First 2019 Chemistry Core Event (i) Glucose - 4 of 5 results exhibited a negative bias (aa) CM-01- SDI of -2.2 (bb) CM-02 - SDI of -2.5 (cc) CM-03 - SDI of -2.0 (dd) CM-04 - SDI of -2.2 (e) Second 2019 Chemistry Core Event (i) ALT

	(Alanine Aminotransferase) - 3 of 5 results exhibited a negative bias (aa) CH-07- SDI of -2.5 (bb) CH-09 - SDI of -2.5 (cc) CH-10 - SDI of -2.1 (ii) Calcium - 4 of 5 results exhibited a negative bias (aa) CH-07- SDI of -2.2 (bb) CH-08 - SDI - -2.0 (cc) CH-09 - SDI of -2.0 (dd) CH-10 - SDI of -2.0 (2) The surveyor further reviewed the records and could not locate documentation verifying the biases had been identified and addressed; (3) The surveyor then reviewed the records with the laboratory supervisor and asked if the biases had been addressed. The laboratory supervisor stated the biases had not been addressed.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures and interview with the laboratory supervisor, the laboratory failed to have a written wet prep procedure. Findings include: (1) During the survey, the laboratory supervisor stated to the surveyor wet prep testing was performed between 07/18/18 and 06/28/19. (2) Later during the survey, the surveyor reviewed written policies and procedures (current and discontinued). A wet prep procedurel procedure could not be located; (3) The surveyor asked the laboratory supervisor if a written procedure for performing wet prep testing existed. The laboratory supervisor stated a procedure had not been written.