Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473191	11/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Cushing Family Practice	2340 E Main, Cushing, 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 11/12/19. The findings were reviewed with the laboratory director/technical consultant and laboratory supervisor at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the testing person failed to sign a proficiency testing attestation statement for 1 of 24 events. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records and identified the following for 1 of 24 events: (a) Second 2019 Microbiology Event - The attestation statement had not been signed by the testing person. (2) The surveyor reviewed the findings with the laboratory supervisor, who stated the attestation statement had not been signed by the testing person.
D2123	HEMATOLOGY

	CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to participate in 1 of 24 proficiency testing events for the 2019 First Hematology Event. Findings include: (1) During the survey, the surveyor reviewed proficiency testing records for 2018 and 2019 and identified the laboratory attained a 0% score for the analytes Erythrocyte Count, Hematocrit, Hemoglobin, Leukocyte Count, MCV (Mean Corpuscular Volume), Platelet Count, White Blood Cell Differential, Granulocytes, Lymphocytes, and Monocytes/Mids for the first 2019 Hematology Event, due to a failure to participate; (2) The documentation in the laboratory records indicated what occurred for the laboratory to not participate; (3) The surveyor reviewed the records with the laboratory supervisor asked them to explain why the laboratory did not participate in the event. The laboratory supervisor stated the following: (a) The laboratory did not receive the proficiency testing samples from the proficiency testing company and contacted (email) the proficiency testing company; (b) The proficiency testing company emailed the laboratory and explained the proficiency samples never arrived to the laboratory due to an investigation of missing proficiency samples lost in transit; (c) The laboratory updated the policy and procedure to reflect the expected ship dates of all future proficiency testing samples.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual and interview with the laboratory supervisor, the laboratory failed to follow written procedures for CBC (Complete Blood Test) testing performed for 2 of 16 patients. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed using the Drew-3 analyzer; (b) The laboratory did not perform manual differential or slide review testing in-house but sent them to a reference laboratory when needed (2) Later during the survey, the surveyor reviewed written procedure titled, "MANUAL DIFF AND SMEAR REVIEW CRITERIA" which stated, (a) "This policy defines the criteria for performance of manual differentials and smear reviews for ordered CBC's." (b) "4. Any of the following suspect flags or values: a. R1,R2,R3(Having to do with red

	cells) P1,P2,P3(Having to do with platelets)." (3) The surveyor reviewed 16 patient records. For 2 of 16 patient records there was no indication the laboratory staff followed their written procedure as follows: (a) Patient #5 tested 01/24/19 at 9:37 am - flagged "R1" (b) Patient #13 tested 03/13/19 at 08:55 am - flagged "R1" (3) The surveyor reviewed the findings with the laboratory supervisor who stated that the procedure had not been followed as indicated above.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for 11 of 15 months. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyor CBC (Complete Blood Count) testing was performed using the Drew-3 analyzer; (2) Later during the survey, the surveyor reviewed the manufacturer's maintenance instructions (contained in the operator's manual section 10.1). The manufacturer required a monthly bleaching; (3) The surveyor then reviewed maintenance records for 15 months (January 2018 through March 2019). There was no evidence the monthly maintenance had been performed between 03/28/18 and 03/19/19; (4) The surveyor reviewed the records with the laboratory supervisor, who stated the monthly maintenance had been performed but not documented. D5429 was cited on the recertification survey performed on 01/17/18.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to use the manufacturer's stated value of control materials for 2 of 9 lots. Findings include: (1) At the beginning of the survey, the director of laboratory operations stated the following to the surveyor: (a) The laboratory supervisor stated to the surveyor CBC (Complete Blood Count) testing was performed using the Drew-3

	analyzer; (b) Three levels of EX-TROL Hematology 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 records for 9 control lot numbers which showed the manufacturer provided ranges had not been uses for 2 of 9 lot numbers as follows: (a) Lot# EX0179L put into use on 06/28/19 and used through 09/30/19 (i) Red Blood Cell Low control - Expected manufacturer range was (2.10 - 2.60) M/L and the laboratory used the range (2.13 - 2.63) M/L (b) Lot# EX1019L put into use on 09/30/19 and was currently in use the day of the survey (i) Lymphocytes % Low control - Expected manufacturer range was (51.5 - 65.5)% and the Laboratory used the range (49.5 - 63.5)% (3) The findings were reviewed with the laboratory supervisor and the laboratory supervisor how the ranges were derived. The laboratory supervisor stated the ranges in use were a result of a clerical error. The laboratory supervisor stated the laboratory policy was to utilize the manufacturer's ranges.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the technical consultant failed to ensure that a person performing moderate complexity testing had been evaluated semiannually during the first year of testing for 1 of 1 testing persons. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records. The following was identified: (a) Testing Person #3 - The initial training for this person was completed on 08/14/18. There was no evidence that a semiannual evaluation had been performed (due 02/19). (2) The surveyor reviewed the records with the laboratory supervisor who stated there were no records to prove the above person had been evaluated semiannually.