Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473191	01/17/2018
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 findings were reviewed with the laboratory supervisor and laboratory director /technical consultant at the conclusion of the survey.
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 supervisor, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed 2016 and 2017 proficiency testing records. The following was identified: (a) 2011 Hematology - 1st Event (i) Platelet Count - The laboratory received a score of 80% (failed 1 of 5 results). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure. (2) The surveyors reviewed the above findings with laboratory supervisor who stated the laboratory had not thoroughly reviewed and evaluated proficiency testing results.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to demonstrate performance specifications prior to patient testing. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to surveyor #2 the laboratory performed CBC (Complete Blood Count) testing on the Drew-3 analyzer; (2) Later during the survey, the laboratory supervisor stated the following to surveyor #2: (a) The analyzer was removed from service on 08/09/17 and sent to the manufacturer for repair; (b) A loaner Drew-3 analyzer (sent by the manufacturer) was put into use on 08/09/17; (c) The manufacturer sent the repaired analyzer back to the laboratory and it was put into service on 09/05/17. (3) Surveyor #2 asked to review the performance specification records for the loaner analyzer and the repaired analyzer. The laboratory supervisor stated that accuracy, precision, reportable ranges had not been demonstrated and reference ranges had not been verified on the Drew-3 loaner analyzer or the repaired analyzer.
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. Findings include: (1) At the beginning of the survey, the laboratory supervisor verified to surveyor #2 CBC (Complete Blood Count) testing was performed using the Drew-3 analyzer; (2) Later during the survey, surveyor #1 reviewed the manufacturer's maintenance instructions (contained in the operator's manual on page 10-7). The manufacturer required the piston lubrication be performed every 6 months; (3) Surveyor #1 then reviewed maintenance records for 24 months (January 2016 through December 2017). There was no evidence the 6 month maintenance had been performed prior to 03/07/17 (due 03/2016 and 09/2016) and after 03/07/17 (due 09/2017); (4) Surveyor #1 reviewed the records with the laboratory supervisor, who stated the 6 month maintenance had not been performed as required.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of records, and interview with the laboratory supervisor, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to surveyor #2 CBC (Complete Blood Count) testing

	was performed using the Drew-3 analyzer; (2) Later during the survey, surveyor #2 reviewed two patient CBC reports - the first report was for an adult female patient with the testing performed on 01/17/2018 at 09:26 am; the second report was for an adult male patient with the testing performed on 01/17/2018 at 10:19 am. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell), Hemoglobin, and Hematocrit, which were: (a) RBC - 4.0 - 6.20 M/uL (b) Hemoglobin - 11.0 - 17.0 g/dL (c) Hematocrit - 35 - 55% (3) The surveyors reviewed the findings with the laboratory supervisor who agreed the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.
D6054	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 annually, after the first year. 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 evaluate testing persons performing moderate complexity testing at least annually. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed personnel records for 4 persons who performed testing in 2016 and 2017. For 1 of 4 persons there was no evidence annual evaluations had been documented as performed by the technical consultant. (a) 2017 (i) Testing Person #4 (2) The surveyors reviewed the findings with the laboratory supervisor, who stated the annual evaluation had not been documented as performed by the technical consultant in 2017 for the above testing person.