Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0690681	(X3) Date Survey Completed 02/13/2018
Name of Provider or Supplier Pike Medical Clinic	**Street Address, City, State** 211 S 3rd Street, Louisiana, MO	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel competency documentation and interview with testing personnel #1, the laboratory failed to perform and document a competency for the technical consultant for moderate complexity testing. Findings: 1. Review of 2016, 2017 competency documentation showed the laboratory failed to perform a competency on the technical consultant for moderate chemistry and hematology testing. 2. Interview with the testing personnel #1 on February 13, 2018 at 11:00 AM confirmed the laboratory failed to perform a competency for the technical consultant for 2016, 2017.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on review of procedure manual, maintenance records and interview, the laboratory failed to document background checks for the pocH-100i hematology analyzer. Findings: 1. Review of the procedure manual showed "Print the background count and store results with the daily patient result tapes." 2. Review of the maintenance records showed a lack of documented background counts for the pocH-100i hematology analyzer. 3. Interview with the testing personnel #1 confirmed the laboratory failed to document the background counts for the pocH-100i. "We do not print off and save the background counts."
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the testing personnel #1, the laboratory failed to perform a positive and negative control 5 of 7 testing days from January 1, 2018 to February 1, 2018 for moderate complex urine toxicology screening. Findings: 1. Review of QC procedures for urine toxicology screening performed on the MedTox scan analyzer showed the laboratory failed to perform a positive and negative control for 5 of 7 patient testing days from January 1, 2018 to January 1, 2018. 2. Interview with the testing personnel #1 on February 13, 2017 at 11:00 AM confirmed, the laboratory did not test a positive and negative control each day of testing for moderate complex urine toxicology on the MedTox scan.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of 2016, 2017 competency documentation and interview with the technical consultant, the technical consultant failed to perform 4 of 12 competency evaluations for 2017. Findings: 1. Review of 2017 employee competencies revealed the technical consultant failed to perform 4 of 12 competencies for testing personnel of moderate complexity testing. 2. Interview with the technical consultant on February 13, 2018 at 11:00AM confirmed the technical consultant failed to perform 4 of 12 annual competencies for 2017.