Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2020484	10/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Family Care Clinic, Llc	306 N Chancery Street, Mcminnville, TN	

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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and interview with the lead lab nurse, the laboratory failed to verify accuracy for Vaginal Wet Prep (Microscopic) at least twice a year by obtaining unsatisfactory scores in 2017-2018. Findings include: 1. Review of PT records for scores during the American Academy of Family Physicians (AAFP) PT 2017-B event and 2018-A event for Vaginal Wet Prep (Microscopic) was 0% for failure to submit PT results in 2017-B and 50% for 2018-A events. 2. An interview with the lead lab nurse on October 10, 2018, at 10:45am, confirmed the laboratory failed to verify accuracy twice a year by obtaining unsatisfactory scores for Vaginal Wet Prep (Microscopic) was 0% for failure to submit PT results in 2017-B and 50% for 2018-A events.
D5303	TEST REQUEST CFR(s): 493.1241(b) The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization. This STANDARD is not met as evidenced by:

	Based on a records review during the chart audit and an interview with the lead lab nurse, the laboratory failed to document written or electronic orders for complete blood count (CBC) from verbal orders on a patient from February 10, 2017. Findings include: 1. A review of one of five CBC records revealed a written or electronic order for a patient's CBC test missing from the chart on February 10, 2017. 2. An interview on October 10, 2018, at 11:30am, with the lead lab nurse confirmed the missing written or electronic order within 30 days of the verbal CBC order for a patient's CBC on February 10, 2017.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the Laboratory's Calibration Verification records for the Hematology analyzer and upon interview with the lead lab nurse, determined the laboratory failed to ensure that calibration verification was performed at six month intervals from November 9, 2016, to April 18, 2018. The findings include: 1. A review of Calibration Verification records for the hematology analyzer revealed no calibration verification documented between November 9, 2016, to April 18, 2018. 2. An interview with the lead lab nurse at approximately 11:35am on October 10, 2018, confirmed the calibration verifications for the Hematology Analyzer documentation could not be located for the period of time between November 9, 2016, to April 18, 2018.