Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1089462	(X3) Date Survey Completed 09/16/2019
Name of Provider or Supplier Dyersburg Family Walk In Clinic	**Street Address, City, State** 193 Jim Adams Drive, Paris, 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
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 observation of the laboratory, review of patient number one test report, the verification of performance specifications (VoPS) studies for the Drew 3 complete blood count (CBC) instrument, the manufacturer operator's manual, and interview with the technical consultant, the laboratory failed to verify the linearity of the Mean Corpuscular Volume (MCV) prior to patient testing in 2019. The findings include: 1) Observation of the laboratory on September 16, 2019 at 8:15 a.m. revealed the Drew 3 CBC instrument in use for patient testing. 2) Review of the first patient reported from the instrument (patient number one) revealed that patient testing for CBC on the Drew 3 CBC instrument began May 30, 2019. 3) Review of the VoPS studies performed for the Drew 3 CBC instrument revealed no verification of linearity for MCV which is used to calculate the hematocrit analyte. 4) Review of the manufacturer's operator manual revealed the following: "Linearity should be evaluated using a commercial linearity material analyzed at least four times for each level. Latex spheres should be used for MCV;" hematocrit is calculated using the red blood cell count and the MCV. 5) Interview with the technical consultant on September 16, 2019 at 10:30 a.m. confirmed the laboratory did not verify the linearity of the MCV in 2019.