Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0859556	07/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lewisville Family Practice Center	1117 South Chestnut Street, Lewisville, AR	

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: . Through a review of Sysmex validation manual, new instrument validation records for the Sysmex XP-300 Hematology analyzer, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to validate method correlation for the Sysmex XP-300 to verify that the manufacturer's reference intervals are appropriate for the laboratory's patient population. As evidenced by: A. A review of the Sysmex validation manual revealed the validation protocol for correlation studies: "Correlation is performed as good laboratory practice to determine equivalency of a new analyzer to the current analyzer or reference method. The Sysmex XP-300 analyzer whole blood correlation should include comparison of the complete blood count and differential parameters." B. The new instrument validation for the Sysmex XP-300 Hematology analyzer revealed the analyzer validation was performed on 2/26/2018 and revealed that no data was present to verify that the manufacturer's reference intervals (normal ranges) are appropriate for the laboratory's patient population. C. Upon request, the laboratory was unable to provide method correlation data for the validation of the Sysmex XP-300 Hematology analyzer. D. In an interview, at 1145 on 7/31/20148, the technical consultant (as listed on the form CMS-209) confirmed that method correlation was not performed as part of the validation of the Sysmex XP-300 Hematology analyzer.