Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2165967	(X3) Date Survey Completed 10/07/2020
Name of Provider or Supplier Mitchell Family Medicine, Llc	**Street Address, City, State** 924 State Hwy 77, Marion, 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 new instrument validation documentation for the Sysmex 300 XN Hematology Analyzer lack of documentation, as well as interviews with staff, it was determined the Laboratory failed to have the director approve verification procedures to ensure they are adequate to determine the accuracy, precision, and other pertinent performance characteristics as evidenced by: A. A review of the verification documentation for Sysmex 300 XN Hematology Analyzer revealed the signature page of the verification procedure was not approved or signed by the laboratory director. B. Upon request, the laboratory could not produce documentation that the laboratory director approved or signed the validation of the Sysmex 300 XN Hematology Analyzer. C. In an interview on 10/07/2020 at 1030, the technical consultant confirmed the validation procedure for the Sysmex 300 XN Hematology analyzer was not approved or signed by the Laboratory Director.