Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0046398	(X3) Date Survey Completed 06/26/2019
Name of Provider or Supplier Salem Memorial District Hospital	**Street Address, City, State** 35629 Hwy 72, Salem, 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
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 review of the performance verification procedures for the Tosoh G8 analyzer for glycohemoglobin testing and interview with the technical supervisor #1, the laboratory failed to verify reference intervals(normal values). Findings: 1. Review of the verification procedures for the Tososh G8 chemistry analyzer for glycohemoglobin showed no verification of normal values. 2. Interview with the technical supervisor #1 on June 26, 2019 at 12:00 PM confirmed the laboratory failed to ensure the verification procedures for normal values for the Tosoh G8 analyzer were appropriate for the laboratory's patient population.