

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0872195	(X3) Date Survey Completed 04/12/2018
Name of Provider or Supplier Mcgehee Family Clinic	Street Address, City, State 1507 South 1st Street, Mcgehee, 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	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Through a review of the new instrument validation performed on 07/25/2017 for the Siemens Dimension ExL, MVP summary data, as well as interviews with staff, it was determined the laboratory failed to validate the reportable range established by the manufacturer for one of twenty-five chemistry tests validated on the Dimension ExL. As evidenced by: A. A review of the validation documentation for Siemens Dimension ExL Chemistry analyzer dated 7/25/2017 revealed the manufacturer's analytic range for Triglycerides as 15.00 to 585. B. A review of the MVP Summary dated 07/25/2017 include the following range validated by testing standard solution: Triglycerides 0.00 to 483.60. The Laboratory did not validate the full analytic range claimed by the manufacturer. C. In an interview at 1145 on 4/12/2018, the Laboratory Director (as listed on the form CMS-209) confirmed the Laboratory did not validate the full reportable range claimed by the manufacturer of the Siemens Dimension ExL.</p>