Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0990194	11/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Gamma Healthcare - St Louis	2938 Telegraph Road, Saint Louis, 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 DXI 600 immunoassay testing and interview with the laboratory director, the laboratory failed to verify reference intervals(normal values). Findings: 1. Review of the verification procedures for the DXI 600 chemistry analyzer for Ferritin, Folate, Free T4, PSA, PTH, T uptake, T4, TSH, Vitamin B12, Vitamin D showed no verification of normal values. 2. Interview with the laboratory director on November 8, 2018 at 11:30 confirmed the laboratory failed to ensure the verification procedures for normal values for the DXI 600 analyzer were appropriate for the laboratory's patient population.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically

	transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the laboratory director, the laboratory failed to ensure test results and patient specific data were reliably sent from the Beckman Coulter DXH 800 hematology analyzer and the DXI 600 chemistry analyzer to the laboratory information system(LIS). Findings: 1. Review of documentation revealed the laboratory failed to check patient data and test results sent from the new hematology analyzer, DXH 800 and the new chemistry analyzer, DXI 600, to the LIS. The new instruments were put into use on March 1 and April 1, 2018. 2. Interview with the laboratory director on November 8, 2018 at 11:30 AM confirmed the laboratory failed to check patient test results and patient specific data electronically transmitted from the DXH 800 and DXI 600 analyzers to the LIS for accuracy.