Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	26D1041510	08/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Gamma Healthcare, Inc - Poplar Bluff	1717 West Maud St, Poplar Bluff, 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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of controls and reagents and interview with the general supervisor #1, the laboratory failed to label controls and calibrators with expiration dates. Findings: 1. Observation of one bottle of Biorad Liquichek 1(lot #68531) and one bottle of Liquichek 2 (lot #68532) showed an open date of 8/15/2019 with no expiration date. 2. Observation of one bottle of high density lipoprotein calibrator showed an open date of 8/9/2019 with an unreadable expiration date. 3. Interview with the general supervisor #1 on August 27, 2019 at 11:00 AM confirmed the laboratory failed to mark expiration dates on prepared controls and calibration material.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must

	be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of maintenance documentation, observation of five of five VWR pipettes, one fume hood and interview with the general supervisor #1, the laboratory failed to define and perform a function check protocol to verify the accuracy of the fume hood and VWR pipettes for microbiology testing. Findings: 1. No documentation was found to show the laboratory defined or performed a function check protocol to verify the accuracy of the volumes of 5 of 5 VWR pipettes since 2017. 2. Observation of the fume hood showed the laboratory had not performed a function check since 2017. 3. Interview with the general supervisor #1 on August 27, 2019 at 11:00 AM confirmed, the laboratory failed to define a protocol and perform a function check to verify the accuracy of the fume hood and the volumes of 5 of 5 VWR pipettes.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) and patient logs and interview with the general supervisor #1, the laboratory failed to perform a positive and negative control each day of testing for moderately complex helicobacter pylori (H. pylori). Findings: 1. Review of QC logs for H. pylori kit testing revealed the laboratory failed to perform a positive and negative external control each day of testing. 2. Review of patient logs revealed three patients were resulted on July 18, 2019. No QC was performed on July 18, 2019. 3. Interview with the general supervisor #1 on August 27, 2019 at 11:00 AM confirmed, the laboratory did not test a positive and negative control each day of testing.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) logs, patient logs, and interview with the general supervisor #1, the laboratory failed to perform a negative and titered positive control for Rheumajet rheumatoid factor (RF) titered testing. Findings: 1 No QC was performed at least once a day for positive titered RF testing. 2. Review of patient logs

	showed 59 patient results were reported out for titered RF from January 2019 to date August 27, 2019. 3. Interview with general supervisor #1 on August 27, 2019 at 11:00 AM confirmed the laboratory reported out titered RF results and failed to perform a negative and known titered control material each day of testing.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of 2018, 2019 instrument comparison documentation and interview with the general supervisor #1, the laboratory failed to perform instrument comparisons two times a year for two of two Beckman Coulter DXI 600 analyzers for the analytes: troponin, human chorionic gonadotropin (HCG), creatine kinase muscle /brain (CKMB), testosterone, and parathyroid hormone (PTH). Findings: 1. Review of the laboratory instrument comparison documentation showed the laboratory failed to perform and document comparison studies for two Beckman Coulter DXI 600 analyzers for troponin, HCG, CKMB, testosterone, and PTH testing for 2018 and to date August 27, 2019. 2. Interview with the general supervisor #1 on August 27, 2019 at 11:00 AM confirmed, the laboratory failed to perform instrument comparisons for the analytes: troponin, HCG, CKMB, testosterone, and PTH testing two times a year.