| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 26D2102945 | 12/09/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Gamma Healthcare Inc - Springfield | 228 E Primrose, Springfield, 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 |
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| **D5305** | TEST REQUEST<br>CFR(s): 493.1241(c)<br><br>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of patient test report and interview with the laboratory director, the laboratory failed to ensure the patient test report included the correct address of the laboratory performing the testing. Findings: 1. Review of the patient test report showed the address as 119 N. Massey Blvd, Nixa, MO 65714. The address of the laboratory is 228 E. Primrose St, Springfield, MO 65807. 2. Interview with the laboratory director on December 9, 2019 at 1:30 PM confirmed the laboratory failed to ensure the patient test report included the correct address of the laboratory performing the testing. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1) |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of ACL elite instrument validation and interview with the laboratory director the laboratory failed to validate the ACL elite after the laboratory physically moved in March 2019. Findings: 1. Review of ACL elite instrument validation for prothrombin time showed no verification of accuracy, precision, reportable range and reference intervals after moving the instrument in March 2019. 2. Interview with the laboratory director on December 9, 2019 at 1:30 PM confirmed the laboratory failed to validate the ACL elite after the laboratory physically moved in March 2019. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of competencies and interview with the laboratory director the technical consultant failed to evaluate and document the performance for one of one testing personnel in 2018. Findings: 1. Review of competencies showed testing personnel #1 did not have documentation for evaluation of performance in 2018. 2. Interview with the laboratory director on December 9, 2019 at 1:30 PM confirmed the technical consultant failed to evaluate and document the performance for testing personnel #1. |