| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 13D0521160 | 02/26/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Syringa Hospital & Clinics | 607 W Main St, Grangeville, ID | |

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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| **D5221** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(d)<br><br>All proficiency testing evaluation and verification activities must be documented.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of proficiency testing (PT) records and an interview with the laboratory manager, the laboratory failed to document the corrective actions for an unacceptable wound culture result on the American Proficiency Institute (API) event 3 in 2018. Findings: 1. A review of the API microbiology results for 2018 event 3, revealed a 50% score for wound culture. 2. A review of the laboratory PT test records for wound culture (WO-02), revealed the laboratory failed to test for and report Staphylococcus aureus. 3. A review of documents revealed the laboratory failed to document corrective actions for the unsatisfactory wound culture result. 4. The laboratory performs approximately 1300 cultures per year. 5. An interview on February 26, 2019 at 11:15 AM, with the laboratory manager, confirmed the laboratory failed to document corrective actions for the missed wound culture. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. |

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| | This STANDARD is not met as evidenced by:<br>Based on records review and an interview with the laboratory manager, the laboratory failed to monitor and document the temperature of the freezer where chemistry reagents were stored during June 7 through July 27, 2018. Findings: 1. A record review of the laboratory freezer temperature charts where Ortho Diagnostics Vitros 350 chemistry reagents were temporarily stored, revealed the temperature was not monitored and recorded between June 7 and July 27, 2018. 2. The laboratory failed to identify and document corrective actions for the freezer temperature not recorded to ensure it maintained at or below -18C, as required by Ortho Diagnostics. 3. An interview on February 26, 2019 at 2:15 PM, with the laboratory manager, confirmed the laboratory did not have record of the temperatures for the freezer. |
| **D5425** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(3)<br><br>The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on an observation, a record review, and an interview with the laboratory manager, the laboratory failed to determine the calibration verification procedures for D-Dimer assays performed on the Alere Triage since February 28, 2018 and blood gases performed on the Opti CCA-TS since the last survey on August 18, 2017. Findings: 1. A record review revealed the laboratory failed to determine the calibration verification procedures for D-dimer and blood gas assays. 2. The laboratory performs approximately 150 D-dimer tests and 50 blood gas tests per year. 3. An interview on February 26, 2019 at 2:05 PM, with the laboratory manager, confirmed the laboratory failed to determine the calibration verification procedures for the tests. |
| **D5437** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(a)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on a record review and an interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions to perform and document calibration procedures for the Cell-Dyn Ruby hematology analyzer after major maintenance on January 27, 2019. Findings: 1. A review of calibration data for the hematology analyzer revealed, the laboratory failed to perform and document |

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| | calibration after the replacement of the analyzer's power supply on January 27, 2019. 2. The laboratory performed approximately 384 complete blood counts in February 2019. 3. A review of the Cell-Dyn operator's manual revealed the laboratory failed follow the manufacturer's requirement for calibration after major maintenance. 4. An interview on February 26, 2019 at 3:45 PM, with the laboratory manager, confirmed the laboratory failed to perform and document calibration activities on the analyzer after the replacement of the power supply. |
| **D5793** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(b)(c)<br><br>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on records review and an interview with the laboratory manager, the laboratory failed to document and review assessment activities that identify and monitor problems with the chemistry and hematology test systems and proficiency testing. Findings: 1. The laboratory failed to identify test system performance requirements and correct problems in calibration and calibration verification procedures for the Cell-Dyn Ruby hematology analyzer, Alere Triage meter for D-dimer, and blood gas procedures on the Opti CCA-TS instrument. See D5425 and D5437. 2. The laboratory failed to document the quality assessment activities for proficiency testing in bacteriology 2018 event 3. See D5221. 3. An interview on February 26, 2019 at 4:45 PM, with the laboratory manager, confirmed the laboratory failed to document the quality assessment activities for the test systems and proficiency testing corrective actions. |