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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>19D0464754   | <b>(X3) Date Survey Completed</b><br><br>08/27/2026 |
| <b>Name of Provider or Supplier</b><br><br>Christus St Frances Cabrini Hospital                                            | <b>Street Address, City, State</b><br><br>3330 Masonic Drive, Alexandria, LA |                                                     |
| 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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| D5441              | <p>CONTROL PROCEDURES<br/>CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the laboratory's Hematology quality control records, manufacturer document, and interview with personnel, the laboratory failed to have established quality control procedures for Complete Blood Count (CBC) testing on the Sysmex XN-550 instrument. Findings: 1. Review of the laboratory's quality control records revealed the laboratory is enrolled in Sysmex's BeyondCare Quality Monitor (BCQM) program. 2. Review the laboratory's policies revealed the laboratory did not update their quality control policies for Complete Blood Count (CBC) testing on the Sysmex XN-550 instrument. Refer to D5403. 3. Review of the manufacturer's memo "Product Notification BeyondCare Quality Monitor (BCQM) v1.3 Additional Notification" revealed "BCQM and Insight for Sysmex XN-and XN-L Series hematology analyzers will reach end-of-life on April 24, 2026. Beginning March 16, 2026, BCQM will serve as the primary quality system for supported analyzers, and all users must fully transition to BCQM v1.3. BCQM and Insight User Actions: Ensure BCQM v1.3 is actively being used, log in using Customer Resource (CRC) credentials, and complete BCQM training through self-enrollment via Caresphere Academy." 4. In interview on August 26, 2026 at 11:30 am, Hematology Technical Consultant 1 confirmed the</p> |

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|              | laboratory had not established quality control procedures to reflect the manufacturer changes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>D6096</b> | <p>LABORATORY DIRECTOR RESPONSIBILITIES<br/>CFR(s): 493.1445(e)(7)</p> <p>(e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance characteristics are identified, and</p> <p>This STANDARD is not met as evidenced by:<br/>An on-site follow-up of the Validation survey was performed at CHRISTUS St. Frances Cabrini Hospital, CLIA ID 19D0464754, on August 26, 2026 through August 27, 2026. Based on review of the laboratory's Plan of Correction, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were documented when deviations from the laboratory's policies occurred. Refer to D5781.</p> |