| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 26D0439378 | 03/01/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| St Louis Cancer Care | 10004 Kennerly Rd Ste 137a, 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 |
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| **D5801** | TEST REPORT<br>CFR(s): 493.1291(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of documentation and interview with testing personnel #3, the laboratory failed to ensure test results and patient specific data was reliably sent from the Abacus 3CP hematology 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, Abacus 3CP, to the LIS. The new instrument was put into use on November 10, 2017. 2. Interview with testing personnel #3 on March 1, 2018 at 10:30 AM confirmed the laboratory failed to check patient test results and patient specific data electronically transmitted from the Abacus 3CP hematology analyzer to the LIS for accuracy. |
| **D6042** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(4)<br><br>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the |

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| | specimen, through sample analysis and reporting of test results;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of quality control(QC) records and interview with the testing personnel #3, the technical consultant failed to review QC for hematology testing performed on the Abacus 3CP. Findings: 1. Review of the QC records for the Abacus 3CP analyzer for complete blood cell counts(CBC) for April - December 2017 and January 2018 revealed the technical consultant failed to review the records to verify instrument accuracy. 2. Interview with the testing personnel #3 on March 1, 2018 at 10:30AM confirmed the technical consultant failed to review quality control records for complete cell counts. |