| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 04D2025496 | 02/09/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Jefferson Regional Cancer Center | 4310 South Mulberry St, Pine Bluff, AR | |

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 |
|---|---|
| **D5431** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(2)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>. Through a review of the AcT diff 2 Hematology Instrument start up results, patient test logs for January 2018, as well as interviews with laboratory staff, it was determined the laboratory failed to ensure function checks were within manufacturer's established limits before patient testing was conducted. As evidenced by: A. The laboratory uses the AcT diff 2 Hematology Instrument to perform Complete Blood Count (CBC) on patient blood samples. B. A review of the maintenance log for the AcT diff analyzer revealed the daily start-up report which includes the background results (pass or fail) for the measured parameters (White Blood Cells, Red Blood Cells, Hemoglobin, and Platelets). C. A review of the daily start-up report and patient testing logs for January 2018 revealed on 1/18/2018 the background result for Platelets was reported as "Failed". The laboratory reported twelve patient CBC results. D. In an interview, at 11:30 on 02/9/2018, the technical consultant (as listed on the form CMS-209) confirmed the laboratory reported patients on days when the background counts did not meet the manufacturer's acceptability requirements. |