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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>44D0975983  | <b>(X3) Date Survey Completed</b><br><br>08/10/2026 |
| <b>Name of Provider or Supplier</b><br><br>Thompson Oncology Group                                                         | <b>Street Address, City, State</b><br><br>9711 Sherrill Blvd, Knoxville, TN |                                                     |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |                                                                             |                                                     |

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| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>D6055</b>              | <p>TECHNICAL CONSULTANT RESPONSIBILITIES<br/>CFR(s): 493.1413(b)(9)</p> <p>(b)(9) unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on laboratory observation, a review of patient test records, testing personnel records, and staff interviews, the technical consultant failed to reevaluate three of ten testing personnel (TP) competency assessments for the use of the Sysmex XN-530 hematology analyzer prior to patient testing, which began in December 2025. The findings include: 1. Observation of the laboratory on 08.10.2026 at 8:30 a.m. revealed that the laboratory used a Sysmex XN-530 (serial number 22895) hematology analyzer for complete blood count (CBC) patient testing. This instrument was new since the last survey date and replaced their Sysmex XS-1000i (serial number 72157). 2. A review of patient test records revealed the laboratory began patient testing with the Sysmex XN-530 on 12.19.2025 (patient number: 680763). 3. A review of testing personnel records revealed no documentation that the technical consultant had reassessed the competency assessment of TP1, TP3, and TP10 for the use of the new Sysmex XN-530 analyzer prior to patient testing, which began on 12.19.2025. 4. The findings were confirmed by an interview with the laboratory services manager on 08.10.2026 at 11:00 a.m.</p> |