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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 44D0309300 | (X3) Date Survey Completed 02/04/2026 |
| Name of Provider or Supplier Tennessee Oncology, Pllc | Street Address, City, State 2390 N Ocoee St, Cleveland, TN | |
| 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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| D5779 | <p>CORRECTIVE ACTIONS CFR(s): 493.1282(a)</p> <p>(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of the laboratory procedure, instrument comparison records, lack of records, and staff interviews, the laboratory failed to follow its policy for corrective action for one of four instrument comparison studies reviewed for results that did not meet the laboratory's established criteria for two of eighteen analytes on the Sysmex instruments used for complete blood count with differential (CBC w/Diff) patient testing in 2025. The findings include: 1. Observation of the laboratory on 02/04/2026 at 1:00 p.m. revealed that the laboratory used the Sysmex XN-430 (Serial 11999) and the Sysmex XN-430 (Serial 12109) for CBC w/Diff patient testing. 2. A review of the laboratory procedure titled "Quality-Inter-Instrument Comparison", section five, "Result/Acceptance," revealed the following: 5.4 If any results failed the comparison, further investigation was required, which included a review of quality controls, calibration records, and maintenance records for each instrument and consultation with the manufacturer for troubleshooting. 5.5 Once the laboratory had completed the corrective action, a repeat method comparison would be performed. 3. A review of the comparison records completed on 11/19/2025 and reviewed by technical consultant one on 01/07/2026 for the Sysmex XN-430 instruments (Serial #'s 11999 and 12109) revealed the following results, which exceeded the laboratory's established criteria: The absolute basophil (Baso#) analyte result was 50.00 with an acceptable criteria of +/- 40%. The percent basophil (Baso%) analyte result was 43.06 with an acceptable criteria of +/- 40%. 4. Documentation of corrective actions or investigation for the Baso# and Baso% analytes was not available on the date of the survey (02/04/2026). 5. An interview</p> |

with technical consultant two on 02/04/2026 at 4:15 p.m. confirmed the survey findings.