| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 44D0310302 | 02/05/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Tennessee Oncology, Pllc | 605 Glenwood Drive, Suite 200, Chattanooga, 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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| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory observation, a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), personnel records, American Proficiency Institute (API) proficiency testing (PT) records, and staff interviews, the laboratory failed to ensure that two of five testing personnel (TP) who performed hematology patient testing also participated in proficiency testing in 2023 and 2024. The findings include: 1. An observation of the laboratory on 02/05/2025 at 9:15 a.m. revealed that it used two Sysmex XN-530 hematology analyzers (ID: 12421 and 12412) for complete blood count (CBC) patient testing. 2. A review of the FORM CMS-209 revealed a total of five persons (TP1, TP2, TP3, TP4, and TP5) who perform moderately complex patient testing. 3. A review of the laboratory's personnel records revealed that all five testing persons performed CBC patient testing in 2023 and 2024. 4. A review of the laboratory's 2023 and 2024 API PT attestation statements revealed that TP1 and TP4 did not participate in any hematology PT events (0 of 6 reviewed). 5. An interview with the Regional Laboratory Operations Manager and Clinic Lab Manager on 02/05/2025 at 1:00 p.m. confirmed that all routine testing personnel did not participate in hematology PT testing. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems |

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| | activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory observation, a review of quality control (QC) records, laboratory policies, lack of documentation, and staff interviews, the laboratory failed to retain peer reporting and Levy-Jennings records for one of two QC lot numbers reviewed in 2024. The findings include: 1. An observation of the laboratory on 02/05/2025 at 9:15 a.m. revealed that it used an Abbott Alinity ci-series chemistry analyzer (ID: AC06855) to perform patient testing. The laboratory used three levels of Technopath Multichem S Plus and IA Plus QC material to verify the analyzer's acceptable performance. 2. A random review of the laboratory's 2024 daily QC records revealed that in May 2024, the laboratory used Technopath Multichem S Plus QC lot number 1205220 for performance verification of their chemistry analyzer. 3. A review of the laboratory's "Quality Assurance" policy revealed the laboratory reviews the "Levy-Jennings report and daily run to confirm all levels are sufficient for running patient samples." The policy further states, "Peer reporting of Monthly QC is sent in for review to the Laboratory Quality Review Supervisor and to be signed off by the Laboratory Technical Director." 4. The laboratory could not provide the Levy-Jennings charts or peer reporting of monthly QC for lot number 1205220. 5. An interview with the Regional Laboratory Operations Manager and Clinic Lab Manager on 02/05/2025 at 1:00 p.m. confirmed the findings. |
| **D3037** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(4)<br><br>(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and staff interviews, the laboratory failed to retain all records for three of twelve proficiency testing events in 2023 and 2024. The findings include: 1. A Review of the laboratory's API PT records revealed the following: - No records were available for the laboratory's 2023 Hematology Event 2. - No records were available for the laboratory's 2023 Chemistry Event 2. - No attestation page was available for the laboratory's 2024 Chemistry Event 1. 2. An interview with the Regional Laboratory Operations Manager and Clinic Lab Manager on 02/05/2025 at 1: 00 p.m. confirmed the findings. |