

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1021272	(X3) Date Survey Completed 02/18/2025
Name of Provider or Supplier Tennessee Plateau Oncology, Pllc	Street Address, City, State 33 West Adams Street, Crossville, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the laboratory's procedure manual, 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 follow their quality assurance plan when three of four testing personnel (TP) did not participate in proficiency testing for all tests they were authorized to perform in 2024. The findings include: 1. An observation of the laboratory on 02/18/2025 at 8:30 a.m. revealed that it used a Sysmex XP-300 hematology analyzer (ID: B3591), Tosoh AIA-900 chemistry analyzer (ID: 11793904), and Alfa Wassermann ACE Axcel chemistry analyzer (ID: 13010064) for patient testing. 2. A review of the laboratory's "Quality Assurance Plan" revealed the following statement: - "All lab personnel will perform PT testing on the instruments in which they are authorized to use and perform patient testing on." 3. A review of the FORM CMS-209 revealed a total of four persons (TP1, TP2, TP3, and TP4) who perform moderately complex patient testing. 4. A review of the laboratory staff's 2024 "Personnel Training\ Competency checklist" and "Evaluation Form" revealed that all four testing personnel were signed off to use the Sysmex XP-300 hematology analyzer, Tosoh AIA-900 chemistry analyzer, and Alfa Wassermann ACE Axcel chemistry analyzer for patient testing. 5. A review of the laboratory's 2024 API PT records revealed that TP2 did not participate in any</p>

hematology proficiency testing events, and TP3 and TP4 did not participate in any chemistry proficiency testing events. 6. An interview with TP1 and the clinic manager on 02/18/2025 at 4:00 p.m. confirmed the survey findings.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on laboratory observation, a review of the manufacturer's instructions for use (IFU), a review of the laboratory's policies, environmental monitoring records, and staff interviews, the laboratory failed to define appropriate freezer temperature ranges, leading to the improper storage of quality control (QC) material used in chemistry testing for four of the four months reviewed in 2024 and 2025. The findings include: 1. An observation of the laboratory on 02/18/2025 at 8:30 a.m. revealed that it used a Tosoh AIA-900 chemistry analyzer (ID: 11793904) for patient chemistry and endocrinology testing. The laboratory used three levels of Biorad Liquichek Tumor Marker Control (Lot: 94981, 94982, and 94983) to validate the daily testing performance on the Tosoh AIA-900. The laboratory stored the Biorad controls in the freezer compartment of their Roper refrigerator (ID: Freezer 1, SN: VSP4445387). 2. A review of the Biorad Liquichek Tumor Marker Control IFUs revealed that the storage requirements are "-20C to -70C." 3. A review of the "General Laboratory Conditions" section in the laboratory's "Quality Assurance" policy revealed that the laboratory's acceptable range for the freezer was -10C to -20C, which is warmer than the manufacturer's requirements. 4. A review of the laboratory's temperature charts for January 2025, December 2024, August 2024, and April 2024 revealed all temperatures recorded for Freezer 1 were warmer than -20C. 5. An interview with TP1 and the clinic manager on 02/18/2025 at 4:00 p.m. confirmed that the laboratory did not define freezer temperature ranges consistent with the manufacturer's instructions, leading to improperly storing QC materials in 2024 and 2025. Key: C = degrees celcius