Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1021272	02/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Tennessee Plateau Oncology, Pllc	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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of instrument printouts and final patient test reports, a review of the manufacturer operator's manual, lack of documentation, and staff interview, the laboratory failed to follow the manufacturer's instructions for verifying five of twenty patient results containing complete blood cell (CBC) result flags. The findings include: 1. Observation of the laboratory on 02/06 /2024 at 8:30 a.m. revealed a Sysmex XP-300 (SN: B3591) analyzer used for CBC patient testing. 2. A review of twenty patient test reports from the Sysmex XP-300 hematology analyzer from 02/02/2024 to 02/06/2024 revealed the following patient CBC test results with a flag: - Date 02/02/2024; Patient 20578; AG flag on the PLT analyte and WL flag on the WBC, LYM%, MXD%, NEUT%, LYM#, MXD#, NEUT# analytes. - Date 02/02/2024; Patient 23432; AG Flag on the PLT analyte. - Date 02/05/2024; Patient 04359; AG Flag on the PLT analyte. - Date 02/05/2024; Patient 544035; AG Flag on the PLT analyte. - Date 02/06/2024; Patient 544014; AG flag on the PLT analyte and WL flag on the WBC, LYM%, MXD%, NEUT%, LYM#, MXD#, NEUT# analytes. 3. A review of the Sysmex XP-300 hematology analyzer Operator's manual (March 2017 Revision) stated the following: -"Flag: WL; Probable sample cause: Incomplete lysing of red blood cells, presence of nucleated red blood cells, increase in large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc; Correction: Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, Check smear, etc." -"Flag: AG; Probable sample cause: Presence of nucleated red blood cells, effects of

	fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc.; Correction: Check smear, etc." 4. The laboratory did not have documentation of corrective actions taken in response to the result flags for patients 20578, 23432, 04359, 544035, and 544014. 5. An interview with the laboratory lead on 02/06/2024 at 1:30 p.m. confirmed the laboratory did not verify results that contained result flags for patients 20578, 23432, 04359, 544035, and 544014. Key: WBC= White Blood Cell count, LYM%= Relative lymphocyte count, NEUT%= Relative neutrophil count, LYM# = Absolute lymphocyte count, NEUT# = Absolute neutrophil count, PLT= Platelet count, MXD%= Relative mixed cell count, MXD# Absolute mixed cell count.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedures, review of quality control (QC) records, and staff interview, the laboratory failed to document the monitoring of QC performance over time for hematology, chemistry, and endocrinology testing in 2022, 2023, and 2024. The findings include: 1. Observation of the laboratory on 02/06/2024 at 8:30 a.m. revealed the following: - A Sysmex XP-300 (SN: B3591) analyzer used for hematology patient testing. - An Alfa Wassermann ACE Axcel Clinical Chemistry System (SN: 13010064) used for general chemistry patient testing. - A Tosoh Bioscience AIA-900 (SN: 11046606) analyzer used for general chemistry and endocrinology patient testing. 2. A review of the laboratory's "Quality Control - Quality Assurance" policy revealed the following statement: - "After every 5 days of testing the quality control material, the testing personnel will review the Levey Jennings chart and complete the Weekly Quality Control-Quality Assurance Log." 3. A review of the laboratory's 2022, 2023, and 2024 QC records revealed no Weekly Quality Control-Quality Assurance Logs documented for hematology, chemistry, and endocrinology testing. A request was made to the laboratory lead on 02/06/2024 at 11:30 a.m. for the Levy-Jennings graphs used by the laboratory for monitoring QC shifts and trends. No records were available. 4. An interview with the laboratory lead on 02/06/2024 at 1:30 p.m. confirmed the laboratory did not monitor Levy-Jennings graphs and document shifts or trends in hematology, chemistry, and endocrinology QC for the last two years.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test

	results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, quality control (QC) records, review of the laboratory's policy, and staff interview, the laboratory failed to ensure aspartate aminotransferase (AST) QC was within acceptable limits prior to reporting one hundred and forty-two patient AST results from 03/09/2022 to 03/15/2022. The findings include: 1. Observation of the laboratory on 02/06/2024 at 8:30 a.m. revealed an Alfa Wassermann ACE Axcel Clinical Chemistry System (SN: 13010064) used for patient AST testing. 2. A review of quality control records from 03/14/22 for the ACE Axcel Clinical Chemistry System revealed unacceptable QC results for the AST analyte on Alfa Wassermann Chemistry Control level 1 (Lot: 1501UNCM). Further investigation revealed level 1 QC was out of range for the AST analyte from 03/09 /2022 to 3/15/2022. A total of 142 AST patient results were reported from 03/09/2022 to 3/15/2022. 3. A review of the laboratory's policy titled "Quality Assurance" revealed the statement "Control results are within acceptable limits before patient samples are reported" in the section for quality control. 4. An interview with the laboratory lead on 02/06/2024 at 1:30 p.m. confirmed the laboratory reported 142 AST patient results when quality control was out of range from 03/09/2022 to 03/15 /2022.