

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D2120027	<b>(X3) Date Survey Completed</b>  01/10/2024
<b>Name of Provider or Supplier</b>  Tennessee Oncology, Pllc	<b>Street Address, City, State</b>  4488 Carothers Parkway Suite 310, Franklin, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3009</b>	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of reagent Safety Data Sheets (SDS), review of Occupational Safety and Health Administration (OSHA) regulations, lack of records, and staff interview, the laboratory failed to ensure OSHA exposure limits were met for Xylene and Formalin used in histopathology processing in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 01/09/2024 at 9:15 a.m. revealed xylene and Formalin in use on the Leica Biosystems ASP6025 tissue processor (SN: 2070) for preparing histopathology slides. 2. Review of the Leica SDS's revealed the following: - 10% Neutral Buffered Formalin SDS states "refer to OSHA 1910.1048 for requirements for handling of formaldehyde solutions." - Xylene SDS states the OSHA PEL (permissible exposure limit) is 100 ppm (parts per million). 3. Review of OSHA guidelines revealed the following: - 1910.1048(c)(1) states "The employer shall assure that no employee is exposed to an airborne concentration of formaldehyde which exceeds 0.75 ppm" per eight hour shift. - 1910.1000 Table Z-1 Limits for Air Contaminants lists the limit for Xylene as 100 ppm. 4. No records for Formalin or xylene monitoring were available for surveyor review. 5. Interview on 01/10/2024 at 3:00 p.m. with the technical consultant confirmed the laboratory used xylene and Formalin in the preparation of histopathology slides. They further confirmed the laboratory did not verify OSHA exposure limits for personnel were met in 2021, 2022, and 2023.</p>
<b>D3039</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5)</p>

Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's fluorescence in situ hybridisation (FISH) policies and procedures, lack of records, and staff interview, the laboratory failed to retain FISH testing annual quality improvement (QI) records for 2021 and 2022. Findings include: 1. Review of the laboratory's "FISH Quality Programs" policy revealed the statement "The laboratory's quality improvement will be evaluated annually." 2. FISH annual QI evaluation records for 2021 and 2022 could not be provided at the time of the survey. 3. An interview on 01/10/2023, at 3:30 p.m. with the laboratory's Technical Director confirmed the laboratory could not provide the 2021 and 2022 FISH annual QI evaluation records for surveyor review.

**D5401**

**PROCEDURE MANUAL**

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Citation 1: Based on observation of the laboratory, review of laboratory policies, lack of records, and staff interview, the laboratory failed to follow their policy for Thermometer Verification for one of six thermometers reviewed in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 01/09/2024 at 08:30 a. m. revealed a Fisherbrand Hygrometer (SN: 111575363) in use for measuring daily room temperature and humidity in the laboratory's histology department. The manufacturer's expiration date for calibration was listed as 05/07/2013. 2. Review of the laboratory's "Timer & Thermometer Verification" policy revealed the following statements: - "Thermometers must be tested against a NIST certified thermometer." - "To assure that the thermometer is operating as intended, this verification step must be performed at the time of installation and at least annually thereafter." 3. There were no verification records for the thermometer used in Histology (SN: 111575363) for measuring room temperature in 2021, 2022, and 2023 for surveyor review. 4. Interview on 01/10/2024 at 3:30 p.m. with the Technical Director confirmed the laboratory failed to follow their policy for thermometer verification in 2021, 2022, and 2023 for the Histology room temperature thermometer. Citation 2: Based on review of patient test records, review of laboratory policies, lack of records, and staff interview, the laboratory failed to follow their policy for digital image retention requirements for one of seven patient records reviewed. The findings include: 1. Review of test records for patient 449647 revealed FISH testing performed on 03/01/2022 (Specimen ID: FST22-012733). 2. Review of the laboratory policy "FISH Retention Requirements" revealed the requirement "Digital images - Kept at least 25 years". 3. Digital images for specimen FST22-012733 could not be provided for surveyor review. 4. Interview on 01/10/2024 at 3:30 p.m. with the Technical Director confirmed the laboratory failed to follow their policy for retention of FISH testing digital images in 2022 when the images for specimen FST22-012733 could not be located.

**D5403**

**PROCEDURE MANUAL**

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Citation 1: Based on observation of the laboratory, review of the laboratory procedure manual, and staff interview, the laboratory procedure failed to include reference ranges for complete blood count (CBC) testing on the dates of the survey (01/09/24 to 01/10/24). The findings include: 1. Observation of the laboratory on 01/09/24 at 9:00 a.m. revealed a Sysmex 550 (SN 16254) in use since 03/2023, and a Sysmex 430 (SN 11115) in use since 01/2024 for patient CBC testing. 2. Review of the laboratory procedure "Sysmex Hematology Analyzer", in use for both analyzers, revealed a lack of reference ranges. 3. Interview with the Technical Consultant and the Hematology Supervisor on 01/10/24 at 3:15 p.m. confirmed there were no reference ranges stated in the procedure used for patient CBC testing. Citation 2: Based on observation of the laboratory, review of the laboratory procedure manual, and staff interview, the laboratory procedure failed to include a protocol for running Quality Control (QC) in the Serum Protein Electrophoresis (SPE) procedure on the dates of the survey (01/09/24 to 01/10/24). The findings include: 1. Observation of the laboratory on 01/09/24 at 9:00 a.m. revealed the Helena SPIFE Touch SPE test system in use for Serum Protein Electrophoresis. 2. Review of the laboratory procedure "SOP SPEP-02 SPIFE Touch SPE and IFE Procedure" revealed no protocol for running QC. 3. Interview with the Technical Consultant and the Chemistry Supervisor on 1/10/24 at 3:15 p.m. confirmed the lack QC protocol in the procedure.

**D6019**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iv)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:  
Based on observation of the laboratory, a review of 2023 College of American Pathologists (CAP) Chemistry Proficiency Testing (PT) results, lack of corrective action for unacceptable results, and staff interviews, the Laboratory Director failed to ensure that corrective action was documented for unacceptable results. The findings include: 1. Observation of the laboratory on 01/09/24 at 9:00 a.m. revealed the Abbott Alinity ci test system (SN-Ac01751, Ai02808, SCM02646) in use for patient chemistry testing. 2. A review of the 1st (C-A) event for 2023 CAP Chemistry PT results revealed unacceptable results for the following analytes: -Cholesterol- 1 of 5 samples -GGT- 3 of 5 samples -TSH- 1 of 5 samples 3. There was no corrective action documented for the unacceptable CAP PT results for the 1st event of 2023. 4. Interviews on 01/10/24 at 1:15 p.m. with the Technical Consultant and the Chemistry Supervisor confirmed there were unacceptable PT scores for the 1st event of 2023 with no corrective action documented.