

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1087357	(X3) Date Survey Completed 10/30/2023
Name of Provider or Supplier Tennessee Oncology Pllc	Street Address, City, State City View Medical Office Building, Nashville, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of patient testing records, personnel records, the Quality Assurance (QA) Program, and an interview with the Laboratory Technical Consultant (TC), the laboratory failed to have documented competencies for three of three testing personnel for serum human chorionic gonadotropin (hCG) testing for 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 10/30/23 at 8:30 am revealed the Henry Shein One Step+ hCG combo test (Lot 667239, Exp date 1/8/25) in use for patient non-waived serum hCG testing. 2. Review of patient testing records revealed 684 serum hCG tests were performed during 2021, 2022, and 2023. 3. Review of personnel records revealed no documented competencies for three of three testing personnel in 2021, 2022, and 2023 for serum hCG testing. 4. Review of the laboratory's Quality Assurance Program revealed the facility "requires competency testing on each laboratory staff member annually". 5. Interview with the Technical Consultant on 10/30/23 at 11:35 am confirmed the laboratory did not have documented competencies for three of three testing personnel for serum HCG testing at the time of the survey.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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</p>

examining specimens.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of patient testing records, procedure manual, and an interview with the Laboratory Technical Consultant (TC), the laboratory failed to have a written procedure for serum human chorionic gonadotropin (hCG) testing on the date of the survey (10/30/23). The findings include: 1.

Observation of the laboratory on 10/30/23 at 8:30 am revealed the Henry Shein One Step+ hCG combo test (Lot 667239, Exp date 1/8/25) in use for patient non-waived serum hCG testing. 2. Review of patient testing records revealed 684 serum hCG tests were performed during 2021, 2022, and 2023. 3. Review of the laboratory procedure manual revealed no procedure available for serum hCG testing. 4. Interview with the Technical Consultant on 10/30/23 at 11:35 am confirmed that the laboratory did not have a written policy for serum hCG testing at the time of the survey.