

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1097417	(X3) Date Survey Completed 08/21/2025
Name of Provider or Supplier Joseph C Lin Md Llc	Street Address, City, State 8903 Harford Rd, Baltimore, MD	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual and record review and interview with the pathologist, the laboratory failed to follow the approved procedures for monitoring turn-around times (TAT) for histopathology testing. Findings: 1. The "Quality Management" procedure states that the quality plan "encompasses all aspects of patient care provided within the laboratory to include outpatient professional services" and that the "performance improvement process is data based. Data to be collected is chosen to reflect:" "... Impact on inter-disciplinary service (ie Turn Around Time)." 2. The "Turn-Around Time and Notification for Delayed Reporting" procedure states the laboratory "has expected turn-around times (TAT) for its test menu" and that "As a parameter for Quality Management, the expected times are to be achieved 90% of the time." The procedure lists a "TAT Expectation" for different services provided by the laboratory, including a TAT of "3 days" for "Biopsies, Surgical - Routine" and a TAT of "4-5 days" for "Biopsies, Surgical requiring addntnl recuts, advanced stains." 3. Record review showed that there was no documentation that TATs were being monitored. 4. During an interview on 08/07/2025 at 10:30 AM, the pathologist stated that the laboratory was not monitoring TATs and that the laboratory would not be aware that a test was beyond the specified "TAT Expectation" unless a patient complained. They confirmed that the laboratory was not following the approved procedure manual.</p>