

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1079612	<b>(X3) Date Survey Completed</b>  10/23/2025
<b>Name of Provider or Supplier</b>  Jkj Pathology	<b>Street Address, City, State</b>  4223 Research Forest Dr, Ste 500, The Woodlands, TX	
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>D0000</b>	An announced survey of the laboratory was conducted on 10/23/2025. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observations, review of laboratory's test statistics and staff interview, the laboratory failed to ensure one of one tissue marking dye was not used beyond its expiration date, the Cancer Diagnostics Inc. (DCI) Blue Tissue Marking Dye, used in grossing of oral pathology samples. Findings included: 1. Surveyor's observations on 10/23/2025 at 0915 hours in the laboratory revealed one DCI's Blue Tissue Marking Dye (REF 0727-2) bottle in use, Lot 8192, sitting on the shelf above the grossing station. The expiration date on the bottle was 2020-07-01. 2. Review of laboratory's test statistics revealed the laboratory tested approximately 600 oral pathology samples annually. 3. In an interview on 10/23/2025 at 0915 hours in the laboratory, the facility's Laboratory Manager (as indicated on submitted Entrance/Exit Conference document) confirmed the findings.</p>