

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0308047	(X3) Date Survey Completed 01/08/2025
Name of Provider or Supplier Laboratory For Kidney Pathology, Inc	Street Address, City, State 1916 Patterson Street Suite 501, 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 a review of the laboratory's procedure manual and staff interview, the laboratory failed to establish a written policy for competency assessments of testing personnel in 2023 and 2024. The findings include: 1. A review of the laboratory's policy and procedure manual revealed no written policy for employee competency assessments. 2. An interview with the Lab Manager on 01/08/2025 at 1:00 p.m. confirmed that the laboratory did not have a written policy for competency assessments.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on laboratory observation, review of the manufacturer's instructions for use, lack of documentation, and staff interview, the laboratory failed to monitor ambient humidity where patient tissue processing occurred for histopathology testing in 2023 and 2024 (18 of 18 months reviewed). The findings include: 1. Observation of the laboratory on 01/08/2025 at 8:00 a.m. revealed a Leica CM 1950 cryostat, Leica Autostainer XL, Leica TP1020 tissue processor, Leica EG1150 H paraffin embedding station, and two Leica RM2255 rotary microtomes used for processing patient tissue samples for histopathology testing. 2. A review of the manufacturer's instructions for use revealed the following environmental specifications: - The Leica CM 1950 requires relative humidity between 20 - 60%. - The Leica Autostainer XL requires relative humidity between 20 - 80%. - The Leica TP1020 requires relative humidity to be less than 80%. - The Leica EG1150 H requires relative humidity to be less than 60% - The Leica RM2255 requires relative humidity to be less than 80%. 3. No humidity monitoring records were available for review from July 2023 to December 2024. 4. An interview with the Lab Manager on 01/08/2025 at 1:00 p.m. confirmed that the laboratory did not monitor laboratory humidity.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on laboratory observation and staff interviews, the laboratory failed to label seven secondary reagent containers used for histopathology processing of patient tissues with all pertinent information. The findings include: 1. Observation of the laboratory on 01/08/2025 at 8:00 a.m. revealed bottles of reconstituted and aliquoted Gomori Trichrome stain, Weigert's Iron Hematoxylin, Congo Red stain, Gill III Hematoxylin, Periodic Acid-Schiff (PAS) stain, Millonig's solution, and Glutaraldehyde phosphate solution in use for histopathology processing. The laboratory did not label the secondary containers with lot numbers and storage requirements. Some containers of Millonig's and Glutaraldehyde phosphate solution also did not contain expiration dates. 2. An interview with the Lab Manager on 01/08/2025 at 1:00 p.m. confirmed that the laboratory did not label secondary containers of reagents used in the automated and manual processing of patient histopathology tissues with all required information.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on laboratory observation, review of the policy and procedure manual, and staff

interviews, the laboratory failed to establish a maintenance protocol for microscopes used for evaluating patient tissues for histopathology testing in 2023 and 2024. The findings include: 1. Observation of the laboratory on 01/08/2025 at 8:00 a.m. revealed one AmScope, two Olympus BX43, and two Vanguard microscopes used for evaluating the quality of patient tissue obtained for histopathology testing. 2. A review of the laboratory's policy and procedure manual revealed no written protocol for maintaining microscopes. 3. An interview with the Lab Manager on 01/08/2025 at 1:00 p.m. confirmed that the laboratory did not establish a protocol for microscope maintenance.