

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2215806	(X3) Date Survey Completed 04/03/2025
Name of Provider or Supplier Rgal Pathology Laboratory	Street Address, City, State 180 Sheree Blvd, Suite 2900, Exton, PA	
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
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: Based on review of laboratory records, lack of documentation, and interview with the Pathology Lab Manager (PLM), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 3 of 3 Olympus BX46 and 1 of 1 Olympus BX45 Microscopes used to perform histopathology slide examinations from 06/29/2023 to the date of survey. Findings include: 1. The operating environment listed in the instruction manual for the Olympus biological microscope states: "microscope should be kept at temperatures between 5C-40C/41F-104F, with a maximum humidity of 80%." 2. On the date of the survey, 04/03/2025 at 10:00 am, the laboratory failed to provide documentation for monitoring room temperatures and humidity to ensure operating conditions were met for 3 of 3 Olympus BX46 and 1 of 1 Olympus BX45 microscope used to perform histopathology slide examinations from 06/29/2023 to 04/03/2025. 3. The laboratory performed 242,000 (CMS-116 estimated annual volume) histopathology slide examinations in 2024. 4. The PLM confirmed the findings above on 04/03/2025 at 10:00 am.</p>
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Personnel Report (CMS-209), competency assessment (CA) records and interview with Pathology Lab Manager (PLM), the Technical Supervisor (TS) failed to evaluate the competency of 16 of 24 testing personnel (TP) that performed histopathology testing in 2024. Findings include: 1. On the day of survey, 04/03/2025 at 9:45 am, review of the laboratory's CA records revealed the TS failed to perform competency assessment on the following TP that performed macroscopic histopathology slide examinations in 2024: - TP8 - TP9 - TP10 - TP11 - TP12 - TP13 - TP14 - TP15 - TP16 - TP17 - TP18 - TP19 - TP20 - TP 22 - TP23 - TP24 2. The PLM confirmed the findings above on 04/03/2025 at 9:45 am.