Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2215806	12/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
Rgal Pathology Laboratory	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
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, lack of documentation, and interview with the Pathology Manager (PM), the laboratory failed to establish and maintain a policy to ensure all complaints and problems reported to the laboratory were documented and investigated when needed for 2 of 2 months from 11/1/2025 to 12/29/2025. Findings include: 1. On the day of complaint investigation, 12/29/2025 at 11:00 am, review of the laboratory Quality Management policy stated, "8.c. Occurrence reports may also be used to document patient or employee complaints and follow up regarding laboratory policies, procedures, or actions that may impact quality or safety." 2. The laboratory could not provide documentation to ensure all complaints and problems reported to the laboratory were documented and investigated as needed for 2 of 2 months from 11/1/2025 to 12/29/2025. 3. The PM confirmed the finding above on 12 /29/2025 at 12:30 pm.
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically

	transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Pathology Manager (PM), the laboratory failed to have an adequate system in place to ensure test results were accurately and reliably sent from the point of data entry to final report destination for 2 of 2 months from 11/1/2025 to 12/29/2025. Findings include: 1. On the day of the complaint investigation, 12/29/2025 at 12:00 pm, the laboratory failed to provide records for the periodic checks performed to verify that patien test results were accurately transmitted between the LIS (Vital Axis) and the EMR (eClinicalWorks) for 2 of 2 months from 11/1/2025 to 12/29/2025. 2. The PM confirmed the findings above on 12/29/2025 at 12:30 pm.