Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2215806	06/29/2023
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a lack of competency records and interview with the Laboratory Director (LD) and Testing Personnel (TP) #2 (CMS 209), the Laboratory failed to establish and follow written policies and procedures to assess 2 of 3 Technical Supervisors (TS) (CMS 209, TS #2, TS #3) and 2 of 3 General Supervisors (GS) (CMS 209, GS #2, GS #3) for their supervisorial responsibilities for the Histopathology examination from 07/14/2021 to the day of the survey. Findings include: 1. On the day of survey, 06/29/2023 at 11:30 AM, a review of the competency record revealed that the laboratory failed to establish a competency assessments procedure for 2 of 3 TS and 2 of 3 GS for their supervisorial responsibilities for Histopathology examination performed from 2021 to 2023. 2. The laboratory filed to provide competency assessment documentation for 2 of 3 TS and 2 of 3 GS for 2021 and 2022. 3. TP #2 confirmed the findings above on 06/29/2023 around 12:50 PM.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of

	accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a review of the Quality Control (QC) log and Interview with the Testing Personnel (TP) #2 (CMS 209), the Laboratory failed to provide documentation of the corrective action taken when 3 of 4 QC results did not meet the laboratory's established acceptable criteria for Histopathology examinations performed using Helicobacter. Pylori stain in January 2021. Findings Include: 1. On the day of survey, 06/29/2023 at 12:18 PM, a review of QC logs revealed that Helicobacter Pylori stain QC was documented as 'Not acceptable' for the following 3 of 4 days that Histopathology examinations were performed in January 2021- 01/03/2023 01/04 /2023 01/05/2023 2. According to the Laboratory's Histopathology staining procedure 'Any problems are noted on the control log with an explanation of what was done to correct the problem'. 3. The Laboratory could not provide documentation of corrective actions taken for the Not acceptable QC results listed above. 4. TP #2 confirmed the findings above on 06/29/2023 at 12:50 PM.