Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	08D2253750	07/23/2026
Name of Provider or Supplier	**Street Address, City, State**	
Rsm Diagnostics Lab Llc	2500 Grubb Road, Suite#120, Wilmington, DE	

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
D0000	A Recertification Survey was conducted on July 23, 2026, at approximately 9:00 AM. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows:
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on interview, facility document review, and facility policy review, the laboratory failed to provide evidence of evaluation of results for 1 of 16 proficiency testing (PT) modules for 2026. Findings included: A facility policy titled, "Handling Proficiency Surveys," dated 03/28/2022, revealed the section titled, "B. Review of survey evaluation reports," included, "2. For survey challenges not formally graded or evaluated by CAP [College of American Pathologists] (non-consensus, invalid method code or no code defined for method, results not submitted or submitted too late for evaluation, etc. [et cetera, and so forth]) the performance of the laboratory will be evaluated against an appropriate comparison group. This evaluation will be performed by the Laboratory Director. If performance by such an alternative evaluation method is outside of acceptable limits, corrective action shall be documented as below." A College of American Pathologists instructions page for the "FCAL [Fecal Calprotectin]-A 2026 Fecal Calprotectin Survey" revealed a handwritten notation, "-100%." A College of American Pathologists report titled "Original Evaluation" for the "FCAL-A 2026 Fecal Calprotectin (FCAL)" survey revealed three of three proficiency testing samples were not graded and were annotated as educational challenge. The report revealed that the Laboratory Director signed the report on 05/28/2026. During an interview on 07/23/2026 at 11:00 AM,

	Technical Supervisor (TS) #1 stated that the laboratory did not document an evaluation comparing the reported results with those of their peer group.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on interview, facility document review, and facility policy review, the laboratory failed to perform correlation of the results of tests performed by different methodologies for 2 of 17 assays reviewed. Findings included: A facility policy titled, "Quality Policy," signed by the Laboratory Director (LD) and Technical Supervisor (TS) #2 on 01/05/2026, revealed the section titled, "Comparability of examination results," stated, "For those examinations performed using different procedures or equipment or at different sites or all these, there shall be a defined mechanism for verifying the comparability of results throughout the clinic at appropriate intervals. Such verification is performed at defined periods of time appropriate to the characteristics of the procedure or instrument." Review of laboratory procedures revealed that the laboratory had two different methods in use for Helicobacter pylori, a "Helicobacter pylori Antigen ELISA Validation" signed by the LD on 02/06/2025, and a procedure for "Gastrointestinal Infection (GI) RT-PCR [reverse transcription polymerase chain reaction] Validation," which included Helicobacter pylori testing, signed by the LD on 05/05/2024. Review of laboratory procedures also revealed that the laboratory had two different methods in use for parasite identification, a "Fecal Parasite Examination-Wet Mount Preparation and Iodine Staining SOP [standard operating procedure]" signed by the LD on 01/17/2026, and a procedure for "Gastrointestinal Infection (GI) RT-PCR Validation" signed by the LD on 05/05 /2024, which included parasite identification as part of "GI Group 3." The facility's "Digestive Marker" reports for the College of American Pathologists (CAP) proficiency testing specimens "Hps-01 Cap" and "Hps-02 Cap" dated 04/09/2025 and "GI Pathogens Multiplex PCR" reports for alternate proficiency testing specimens "Pcr-01 Alt Pt" and "Pcr-02 Alt-PT" dated 07/17/2026 revealed both methods were being used to report Helicobacter pylori results. A sample "Total GI Comprehensive Stool Profile" report dated 07/19/2026 used by the laboratory revealed both methods were being used to report parasite identification. During an interview on 07/23/2026 at 5:05 PM, the LD, TS #1, and TS #2 were each asked for documentation for the correlation between two procedures for Helicobacter pylori and parasite identification. Each responded that the correlation studies were not performed.