Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	08D2253750	11/13/2025
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 Complaint Investigation Survey was conducted on November 13, 2025 at approximately 9:00 AM. Complaint #15591 was investigated and was substantiated. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows:
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) (b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on interview, document review, and facility policy review, the laboratory failed to test 5 of 5 hematology proficiency testing (PT) samples in the same manner as the patient sampled were tested. Findings included: The laboratory "Standard Operating Procedure" effective 03/04/2022, revealed, "2. All testing of survey samples is to be handled in exactly the same manner as patients specimens are tested." The laboratory "PT Event Participation Log" revealed the laboratory participated in the College of American Pathologists (CAP) PT event FH16-C for hematology. The PT Event Participation Log indicated the PT samples were received in the laboratory on 09/18 /2025, tested on 09/18/2025, and the results were submitted on 10/02/2025. The "CAP" attestation form for FH16-C, which indicated the undersigned performed the analyses on the specimens in the same manner as regular patient specimens, was signed by three different testing personnels (TP). The instrument printouts reviewed showed that each of the five PT samples was tested by three different TPs. During an interview on 11/13/2025 at 10:30 AM, the Technical Consultant/Technical Supervisor /General Supervisor/Testing Personnel stated multiple TPs performed the PT samples, but they should have been performed by one TP.

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on interview and facility policy review, the laboratory failed to have a written procedure for the performance of quality control (QC) on gram stains. This deficiency had the potential to affect all patients who received services from the laboratory. Findings included: During the survey, it was noted the laboratory implemented a procedure for weekly QC of gram stain using American Type Culture Collection (ATCC) strains. However, review of the "Media Preparation and Quality Control (QC) -SOP {Standard Operating Procedure]" approved by the Laboratory Director on 09/292025, did not reveal a procedure for the weekly QC of gram stains. During an interview on 11/13/2025 at 1:00 PM, Testing Personnel (TP) #1 and TP #2 described how they performed QC on gram stains, but stated there was not a written procedure.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on interview, document review, and facility policy review, the laboratory failed to follow manufacturer's instructions for 1 (antibiotic sensitivity testing [AST]) of 1 procedure reviewed. Findings included: The laboratory "Microbial Cultures Validation" procedure effective 06/20/2023 and signed by the Laboratory Director (LD) 06/20/2023, for the "5.11 Antibiotic Sensitivity Test" revealed "5.11.2 Procedure: 1. The sterile cotton swab tip was dipped into the sterile water until the cotton tip was fully saturated and used to take up 1-2 colonies. 2. Starting at the outside of the plate a lawn culture was made across the entire plate a total of 4 times

	rotating the plate in 90 degree turns." The undated "Technical Data" for the "Microexpress Penicillin P 10 units" revealed "2. Select 3-4 colonies from subcultured slant or plate and transfer them into 5 mL [milliliter] of sterile 0.85% saline, vortex the suspension and adjust the turbidity to yield a uniform suspension matching 0.5 McFarland standard. 3. Incubate the broth at 35 [degrees] C [Celsius] - 37 [degrees]C until it achieves or exceeds the turbidity of the 0.5 McFarland's barium sulphate standard. This results in a suspicion containing approximately 1-2 X [times] 10 [to the eight degree] cfu/mL [colony forming unit per milliliter]. 4. Adjust the turbidity to the barium sulphate standard. For the diluents use sterile broth or sterile saline. The turbidity of the standard and the test inoculums should be compared by holding both tubes in front of a white background and finely divided lines or by use of photometric device. 5. Within 15 minutes of adjusting the turbidity of the inoculum, immerse a sterile cotton swab into the properly diluted inoculum and rotate it firmly several times against the upper inside wall of the tube to express excess fluid. 6. Inoculate the entire agar surface of the plate three times, rotating the plate 60 [degrees] between streaking to obtain even inoculation. Swab the rim of the agar bed too." During an interview on 11/13/2025 at 1:35 PM, Testing Personnel (TP) #1 and TP #2 were asked to describe the technique for AST using the antibiotic discs. TP #2 stated the procedure was to do a direct inoculation of the plates from the primary culture plate using a sterile cotton swab moistened with sterile water. During an interview on 11/13 /2025 at 3:10 PM, the Technical Consultant/Technical Supervisor/General Supervisor /Testing Personnel was asked why the laboratory's AST procedure did not follow the manufacturer's instructions and he responded that the procedure in use was a procedure used in another laboratory where he worked. At 4:45 PM, he was asked to provide documentation to support the use of a modified procedure for AST and he stated he had no documentation and acknowledged the laboratory was not following the manufacturer's instructions for AST.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on interview, document review, and facility policy review, the laboratory failed to establish through validation the performance specifications for 1 (antibiotic sensitivity testing [AST]) of 1 procedure reviewed. Findings included: The laboratory "Microbial Cultures Validation" procedure effective 06/20/2023 and signed by the Laboratory Director (LD) 06/20/2023, for the "5.11 Antibiotic Sensitivity Test" revealed "5.11.2 Procedure: 1. The sterile cotton swab tip was dipped into the sterile water until the cotton tip was fully saturated and used to take up 1-2 colonies. 2. Starting at the outside of the plate a lawn culture was made across the entire plate a total of 4 times rotating the plate in 90 degree turns." The undated "Technical Data"

	for the "Microexpress Penicillin P 10 units" revealed "2. Select 3-4 colonies from subcultured slant or plate and transfer them into 5 mL [milliliter] of sterile 0.85% saline, vortex the suspension and adjust the turbidity to yield a uniform suspension matching 0.5 McFarland standard. 3. Incubate the broth at 35 [degrees] C [Celsius] - 37 [degrees]C until it achieves or exceeds the turbidity of the 0.5 McFarland's barium sulphate standard. This results in a suspicion containing approximately 1-2 X [times] 10 [to the eight degree] cfu/mL [colony forming unit per milliliter]. 4. Adjust the turbidity to the barium sulphate standard. For the diluents use sterile broth or sterile saline. The turbidity of the standard and the test inoculums should be compared by holding both tubes in front of a white background and finely divided lines or by use of photometric device. 5. Within 15 minutes of adjusting the turbidity of the inoculum, immerse a sterile cotton swab into the properly diluted inoculum and rotate it firmly several times against the upper inside wall of the tube to express excess fluid. 6. Inoculate the entire agar surface of the plate three times, rotating the plate 60 [degrees] between streaking to obtain even inoculation. Swab the rim of the agar bed too." During an interview on 11/13/2025 at 1:35 PM, Testing Personnel (TP) #1 and TP #2 were asked to describe the technique for AST using the antibiotic discs. TP #2 stated the procedure was to do a direct inoculation of the plates from the primary culture plate using a sterile cotton swab moistened with sterile water. During an interview on 11/13/2025 at 3:10 PM, the Technical Consultant/Technical Supervisor /General Supervisor/Testing Personnel was asked why the laboratory's AST procedure did not follow the manufacturer's instructions and he responded that the procedure in use was a procedure used in another laboratory where he worked. At 3:15 PM, he was asked for documentation that the AST procedure in use had been validated. At 4:45 PM, he was asked to provide documentation to support the use of a modified procedure for AST and he stated he had no documentation and acknowledged the laboratory was not following the manufacturer's instructions for AST.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on interview and record review, the laboratory failed to indicate the correct specimen source on 18 (Patients #1 - #18) of 18 patient reports reviewed. Findings included: The "Upper Respiratory Culture Bacteriology Culture & Sensitivity" for Patients #1 - #18 for the timeframe 11/2024, 01/2025, and 05/2025, all indicated "Nasopharyngeal swab" as the type of specimen source collected. During an interview on 11/13/2025 at 5:18 PM, the Technical Consultant/Technical Supervisor/General Supervisor/Testing Personnel was asked what specimen type was used to perform the test and he stated that the throat swab was used to perform the bacterial culture, the nose swab was used to perform the fungal culture, and the nasopharyngeal swab was used for viral testing. During an interview on 11/13/2025 at 5:28 PM, the Laboratory Manager stated nasopharyngeal swab was the default specimen type in the laboratory

	information system (LIS) for the upper respiratory culture bacteriology culture and sensitivity and that would be fixed by adding a drop-down in the LIS menu that would allow selection of the correct specimen type.