Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	08D2253750	09/26/2025
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 Recertification Survey was initiated on September 26, 2025 at approximately 1:45 PM. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows: It was determined that Immediate Jeopardy (IJ) existed for the following condition-level deficiencies: 42 CFR 493.801 Enrollment and Testing of Samples 42 CFR 493.1201 Bacteriology
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on interview and facility document and policy review, the laboratory failed to enroll in a proficiency testing (PT) program approved by the United States Department of Health and Human Services (HHS) for all regulated analytes in the specialties and subspecialties in which patient testing was performed. This deficiency was identified with 13 of 14 specialties/subspecialties for which the laboratory performed testing. It was determined the facility's non-compliance with one or more requirements of participation had caused, or was likely to cause, serious injury, serious harm, serious impairment, or death to patients. The Immediate Jeopardy (IJ) was related to 42 CFR 493.801, D2000. The IJ was identified during the survey on 09 /26/2025. The survey team notified the Laboratory Director (LD), Laboratory

	Manager (LM) #10, and the Managing Partner of the IJ and provided the IJ template on 09/30/2025 at 10:15 AM. Findings included: A facility policy titled, "Handling Proficiency Surveys," dated 03/04/2022 and signed as approved by the LD on 03/04 /2022, revealed, "Policy: To comply with state and federal regulations, the laboratory subscribes to an external proficiency testing program from CLIA for analytes where surveys are available." The policy specified, "The surveys to which the laboratory subscribes are determined on the basis of the specific test procedures performed in the laboratory. The available CLIA surveys are reviewed annually at the time of the survey reorder to determine what surveys should be added or deleted based on changes in test services and/or CLIA survey offerings." The facility's "Clinical Laboratory Improvement Amendments (CLIA) Application for Certification" (Form CMS-116), signed by the LD on 07/01/2024, revealed the LD disclosed that the laboratory performed testing for the following specialties/subspecialties: microbiology (including bacteriology, mycology, parasitology, and virology), diagnostic immunology (including general immunology), chemistry (including routine, urinalyses, endocrinology, and toxicology), and hematology. The facility's current "Clinical Laboratory Improvement Amendments (CLIA) Application for Certification" (Form CMS-116), signed by the LD on 09/30/2025, revealed the LD disclosed that the laboratory performed testing for the following specialties /subspecialties: microbiology (including bacteriology, mycobacteriology, mycology, parasitology, and virology), diagnostic immunology (including general immunology), chemistry (including routine, urinalyses, and endocrinology), and hematology. An undated "[laboratory name] Test List" revealed the laboratory's testing menu included routine chemistry testing, hematology testing, urinalyses, bacteriology culture and sensitivities, mycology culture and sensitivities, immunology testing, and ova and parasite identification. A sample of the facility's test reports i ndicated the laboratory performed testing for regulated analytes in bacteriology (including cultures and sensitivities), mycobacteriology, mycology (including cultures and sensitivities), parasitology, virology, chemistry, and endocrinology, which were subject to PT. On 09 /26/2025 at 3:40 PM, the LD was asked to provide documentation of enrollment in a PT program. The LD could not produce documentation of enrollment in an HHS-approved PT program. During an interview on 09/26/2025 at 3:49 PM, the LD stated they did not enroll in an HHS-approved PT program when they started patient testing in July of 2023 because they had a low volume of testing. He stated that they did enroll in the College of American Pathologists (CAP) PT in the specialty of Hematology and just received their first challenge, which they had not yet submitted.
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on record review, interview, and facility document and policy review, the laboratory failed to meet the requirements for the subspecialty of bacteriology, despite performing a total of 2,331 bacteriology tests during the timeframe from 09/01/2023 through 09/26/2025 . It was determined the facility's non-compliance with one or more requirements of participation had caused, or was likely to cause, serious injury, serious harm, serious impairment, or death to patients. The Immediate Jeopardy (IJ) was related to 42 CFR 493.1201, D5002. The IJ was identified during the survey on 09

	/26/2025. The survey team notified the Laboratory Director (LD), Laboratory Manager (LM) #10, and the Managing Partner of the IJ and provided the IJ template on 09/30/2025 at 10:15 AM. Findings included: 1. The facility failed to perform the required weekly quality control for gram stains. (Refer to D5503) 2. The facility failed to perform the required quality control of discs used for antibiotic susceptibility testing. (Refer to D5507) 3. The facility failed to ensure they did not use discs for antibiotic susceptibility testing that were beyond the manufacturer's expiration date. (Refer to D5417) 4. The facility failed to check each batch of prepared media for its ability to support growth. (Refer to D5477)
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, interview, and review of manufacturer's information for quality control (QC) materials, the laboratory failed to use the chemistry QC materials within the open vial stability date. This was noted for 2 of 2 vials observed. Findings included: The undated manufacture's information for "Multichem S Plus" (QC material) revealed the section titled, "Storage and Stability" specified, "This product will be stable until the expiration date when stored unopened between -20 [degrees] C [Celsius] and -80 [degrees] C." The package insert also specified, "Once the control material is thawed and opened, it should be stored tightly capped at 2 [degrees] C to 8 [degrees] C. Analytes are stable for 10 days under these conditions with the following exceptions: Glucose will be stable for 7 days. Carbon Dioxide (Bicarbonate) will be stable for 7 days. Lactate (Lactic Acid) will be stable for 7 days. Unsaturated Iron Binding Capacity (UIBC) will be stable for 4 days. Bilirubin, Direct will be stable for 4 days. Bilirubin, Total will be stable for 4 days. Phosphorus will be stable for 4 days. Triglycerides will be stable for 4 days." During a concurrent observation and interview on 09/26/2025 at 3:10 PM, Technical Consultant (TC)/Testing Personnel (TP) #6 was asked for the QC materials used for the laboratory's Beckman AU480 analyzer. TC/TP #6 produced two vials of QC material labeled, "Multichem S Plus Level 1, Lot number CH101PLA" and "Multichem S Plus Level 3, Lot number CH101PLA." The vials were labeled with a handwritten date of "9/3." During an interview on 09/26/2025 at 3:14 PM, TC/TP #6 stated that the date written on the QC vials ("9/3") was the date they were opened and put into use. TC/TP #6 stated the QC vials could be used until the manufacturer's expiration date printed on the vials. During a follow-up interview on 09/26/2025 at 3:20 PM, TC/TP #6 stated they were unaware the manufacturer instructed that the QC vials' stability were impacted once the products were opened.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to ensure they did not use antibiotic susceptibility discs that were beyond the manufacturer's expiration date for antibiotic susceptibility testing. This was noted for 28 out of 28 vials of discs observed. Findings included: During a concurrent interview and observation on 09/26 /2025 at 2:05 PM, Testing Personnel (TP) #8 was asked for the antibiotic susceptibility discs currently in use by the laboratory. TP #8 provided four boxes of antibiotic susceptibility disc vials labeled, "Stool Culture," "Antifungal," "Urine Culture," and "Throat Culture." Each box contained vials of "Biogram Antimicrobial Susceptibility Discs." The observation revealed the following antibiotic susceptibility discs were expired: - Stool Culture box: - Ampicillin- lot number AS10102303- expiration date 02/2024 - Tetracycline- lot number TE302309- expiration date 11 /2024 - Ceftazidime- lot number CA2302314- expiration date 12/2024 - Imipenem- lot number IPM102219- expiration date 06/2024 - Imipenem- lot number IPM102315- expiration date 09/2023 - Aztreonam- lot number AT302305- expiration date 11/2024 - Aztreonam- lot number AT302310- expiration date 08/2024 - Cefepim- lot number CPM302311- expiration date 01/2025 - Levofloxacin lot number LE52310- expiration date 11/2024 - Cefuroxime- lot number CXM302309- expiration date 11/2024 - Urine Culture box: - Trimethoprim- lot number COT252304- expiration date 07/2024 - Imipem- lot number IPM2219- expiration date 09/2023 - Nitrofurantoin- lot number NIT3002316- expiration date 11/2024 - Netilmicin- lot number NET102303- expiration date 08/2024 - Cefepim- lot number CPM302311- expiration date 01/2025 - Norfloxacin- lot number NX102304- expiration date 08/2024 - Ofloxacin- lot number OFS2309- expiration date 10/2024 - Gentamicin- lot number GEN102317- expiration date 12/2024 - Levofloxacin- lot number LE52218- expiration date 03/2024 - Throat Culture box: - Cefoxitin- lot number CX302216- expiration date 03/2024 - Amoxycillin- lot number AMC102227- expiration date 11/2023 - Gentamicin- lot number GEN102317- expiration date 12/2024 - Azithromycin- lot number AZM152211- expiration date 01/2024 - Ciprofloxacin- lot number CIP52307- expiration date 08/2024 - Ampicillin- lot number AMP102317- expiration date 02 /2025 - Doxycycline- lot number DOX302317- expiration date 10/2024 - Antifungal box - Cefuroxime- lot number CXM302309- expiration date 11/2024 - Ceftazidime lot number CAZ2302314- expiration date 12/2024 During an interview on 09/26/2025 at 2:15 PM, TP #8 did not provide an explanation as to why antibiotic susceptibility testing was being performed with expired antibiotic susceptibility discs. During an interview on 09/26/2025 at 2:18 PM, Technical Consultant (TC)/Technical Supervisor (TS)/General Supervisor (GS)/Technical Personnel (TP) #3 stated the expired antibiotic susceptibility discs were still being used despite exceeding their expiration dates, because they continued to work. A concurrent observation and interview on 09 /26/2025 at 2:22 PM revealed three petri dishes with bacteriological subcultures that were removed from the autoclave by TP #8 at the surveyor's request. Each petri dish had susceptibility discs embedded in the cultures and was marked with a four-digit number. TP #8 stated the four-digit numbers were patient accession numbers correlating to Patients #1, #2, and #3. TP #8 confirmed the antibiotic susceptibility discs utilized for these three patients were from the boxes of expired antibiotic susceptibility discs.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media

	for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. This STANDARD is not met as evidenced by: Based on interview and facility policy review, the laboratory failed to check each batch of prepared media for its ability to support growth. This was noted for 20 out of 20 batches of prepared media stored in the laboratory's refrigerator. Findings included: A facility policy titled, "Microbial Cultures Validation (MCV)," signed as approved by the Laboratory Director (LD) on 06/20/2023, revealed the policy did not address any routine checks or quality control (QC) measures required for prepared media. During an interview on 09/26/2025 at 2:45 PM, Testing Personnel (TP) #8 was asked for documentation of routine checks or QC measures taken for batches of prepared media, but TP #8 was unable to provide any documentation. During an interview on 09/26/2025 at 2:50 PM, Technical Consultant (TC)/Technical Supervisor (TS)/General Supervisor (GS)/TP #3 stated prepared media was not being tested with QC organisms before use.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a)(2) Each week of use for Gram stains. This STANDARD is not met as evidenced by: Based on interview and facility policy review, the facility failed to perform required weekly quality control for gram stains for 2 of 2 years reviewed. Findings included: A facility policy titled, "Microbial Cultures Validation (MCV)," signed as approved by the Laboratory Director (LD) on 06/20/2023, revealed no information related to performing quality control for gram stains. On 09/26/2025 at 2:55 PM, Testing Personnel (TP) #8 was asked for documentation of required weekly quality control for gram stains with known organisms but none were provided. During an interview on 09/26/2025 at 2:58 PM, Technical Consultant (TC)/Technical Supervisor (TS)/General Supervisor (GS)/Technical Supervisor (TS) #3 stated that quality controls were not being performed for gram stains.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by:

	Based on interview and facility policy review, the facility failed to perform required quality control (QC) testing of antibiotic susceptibility discs used for antibiotic susceptibility testing. This was noted for 28 of 28 vials of antibiotic susceptibility discs observed. Findings included: A facility policy titled, "Microbial Cultures Validation (MCV)," signed as approved by the Laboratory Director (LD) on 06/20 /2023, revealed the policy did not address the performance of QC testing on antibiotic susceptibility discs. During an observation on 09/26/2025 at 2:05 PM, Testing Personnel (TP) #8 was asked for the antibiotic susceptibility discs currently in use by the laboratory. TP #8 provided four boxes of antibiotic susceptibility disc vials labeled, "Stool Culture," "Antifungal," "Urine Culture," and "Throat Culture." The boxes contained a total of 28 vials of antibiotic susceptibility discs, all of which were beyond their manufacturer's expiration date. During an interview on 09/26/2025 at 2: 32 PM, TP #8 was asked for documentation of daily QC testing of antibiotic susceptibility discs but none was provided. During a follow-up interview on 09/26 /2025 at 2:38 PM, TP #8 confirmed the laboratory was not using QC materials, including known organisms, to test their antibiotic susceptibility discs for expected results.