Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1065892	10/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Regional Pathologists, Inc	140 Sylvan Avenue, Englewood Cliffs, NJ	

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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratories New Jersey (NJ) State License, Proficiency Testing (PT) and interview with the Technical Supervisor (TS) the laboratory failed to be in compliance with NJ Administrative code N.J.A.C. 8:44-2.5 (b)3. for calendar years 2023 and 2024. The finding includes: 1. N.J.A.C. 8:44-2.5(b) 3. states Laboratories shall: iii. Maintain records of all proficiency testing results in surveys in which they participate and make such records, including results, interpretations and cumulative performance data routinely available to the Department of Health and Senior Services. 2. Review of the PT records for all PT events in 2023 and 2024 revealed that the reports were only copied to Centers for Medicare and Medicaid Services (CMS) and New York State Department of Health and not the NJ Department of Health and Senior Services. 3. The TS confirmed on 10/8/24 at 11:30 am the laboratory failed to make PT performance data for Immunology, Urinalysis, Bacteriology, Parasitology and Virology routinely available to the NJ Department of Health and Senior Services.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Techincal Supervisor (TS), the laboratory failed to establish a detailed procedure for Biannual Assessment (BA) from 6/8/22 to 10/8/24. The TS confirmed on 6/8/22 at 1:15 pm t laboratory did not have a BA procedure..
D5315	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. This STANDARD is not met as evidenced by: Based on surveyor review of Final Reports (FR), Histopathology records and interview with the Techincal Supervisor (TS) the laboratory referred the evaluation of histopathology slides to a non-CLIA-certified laboratory from 6/8/22 to 10/8/24. The TS confirmed on 10/8/24 at 12:45 pm that histopathology slides were reviewed and resulted from a non-CLIA-certified laboratory.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratories Individualized Quality Control Plan (IQCP) for Bacteriology, mycology parasitology, and virology tests performed on the Bio-fire analyzer and interview with the Technical Supervisor (TS), the laboratory failed to monitor, assess, and when indicated, correct problems identified in the preanalytic system from 6/8/22 to 10/8/24. The finding includes. 1. The Quality Assesment did not establish written policies and procedures for the frequency in which the QA monitors the Quality Control Plan (QCP). 2. The TS confirmed on 10/8 /24 at 12:00 PM that the laboratory failed to establish written policies and procedures for the frequency in which the QA monitors the QCP.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 surveyor observation of Acetic Acid 3% reagent and interview with the Techincal Supervisor (TS), the laboratory failed to discard expired reagents from 5/31

	/2024 to 10/8/24. The findings include: 1. Avantik Acetic Acid, 3% Lot # 171358 expired 5/3/2024 2. Approximately 200 patients were run and reported 3. The TS confirmed on 10/8/24 at 10:30 am that the laboratory used expired reagent.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor review of an Individualized Quality Control Plan (IQCP) and interview with the Techincal Supervisor (TS) the laboratory failed to perform a Risk Assesment (RA) on Testing Personnel TP) as required for testing performed on the Bio-fire analyzer from 6/8/22 to 10/8/24. The findings include: 1) There was no documented evidence that an RA on TP was performed in the IQCP used for the Bio-fire analyzer. 3) The TS confirmed on 10/8/24 at 11:00 am the laboratory failed to have the above mention RA in an approved IQCP for the Bio-fire analyzer.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: a) Based on surveyor review of the Procedure Manual (PM), and interview with the Technical Supervisor(TS), the laboratory failed to perform and document lot to lot verification for Bacteriology, mycology parasitology, and virology tests performed on the Bio-fire analyzer analyzer from 6/9/22 to 10/8/24. The findings include: 1. There was no documented evidence lot to lot verification was performed on FilmArray GI control panels. 2. The TS confirmed on 10/8/24 at 12:10 pm, the laboratory failed to perform lot to lot verification on all FilmArray GI control panels. 48354 B) Based on surveyor review of the Procedure Manual (PM), Urinalysis Lot to Lot Test Log (ULL) and interview with the Technical Supervisor(TS), the laboratory failed to perform and document lot to lot verification for Urinalysis tests performed on the Arkray 4030 analyzer from 10/1/24 to 10/8/24. The findings include: 1. There was no documented evidence lot to lot verification was performed on Aution Arkray test strips lot # 9EB4B27. 2. The TS confirmed on 10/8/24 at 12:10 pm, the laboratory failed to perform lot to lot verification on all Aution Arkray test trips.

D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of Quality Control Verification (QCV) records and interview with the Technical Supervisor, the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment used on the IQ200 and Arkay 4030 for Urinalysis testing from 6/8/22 to 10/8/24. The finding includes: 1. There were no QCV records available for review for the IQ200 and Arkray 4030. 2. The TS confirmed on 10/8/24 at 12:20 pm, the assayed values of QC material were not verified before patient testing.
D5805	TEST REPORT CFR(s): 493.1291(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 surveyor review of the Test Reports (TR) for Bacteriology, mycology, parasitology, and virology tests performed on the Bio-fire analyzer and interview with the Technical Supervisor (TS) the laboratory failed to ensure the TR included all the required information from 6/8/22 to 10/8/24. The findings include: 1. TR did not include the address of the elaborately where testing was performed. 2. The TS confirmed on 10/8//24 at 12:00 pm, the laboratory failed to ensure the TR included all the required information.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to

	identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on the lack of Biannual Assessment (BA) records and interview with the Techincal Supervisor (TS), the Laboratory Director (LD) failed to ensure BA was performed to evaluate the laboratory's performance accurately from 6/8/22 to 10/8/24. The TS confirmed on 10/8//24 at 1:00 pm the BA was not performed to evaluate the laboratory's performance accurately.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the lack of Quality Control Verification (QCV) records and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure QCV procedures were established from 6/8/22 to 10/8/24. The findings include: 1. The LD failed to establish QCV procedures for the IQ200 and Arkray 4030 used for Urinalysis testing. 2. The TS confirmed on 10/8/24 at 12:00 pm, the LD failed to ensure QCV procedures were established.