Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0920750	06/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Satish A Shah Md Pllc	207 N Broad Street, Philadelphia, 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
D0000	A routine recertification survey was conducted by the Pennsylvania State Agency for Rittenhouse Hematology & Oncology, LLC on 06/11/2026. The laboratory was found out of compliance with the following conditions: 493.1230 Condition: General laboratory systems. 493.1250 Condition: Analytic systems. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on lack of documentation, review of the laboratory's procedure manual and interview with the Medical Assistant (MA), the laboratory failed to meet applicable general laboratory systems requirements in 493.1231 for 2 of 2 years from 07/30/2024 to date of survey. Refer to D5205
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

	This STANDARD is not met as evidenced by: Based on lack of documentation, review of laboratory procedures, and interview with the Medical Assistant (MA), the laboratory failed to establish and maintain a policy to ensure all complaints and problems reported to the laboratory are documented and investigated when needed for 2 of 2 years from 07/30/2024 to the day of survey. Findings include: 1. On the day of survey, 06/11/2026 at 10:45 am, the laboratory could not provide a policy to ensure all complaints and problems reported to the laboratory are documented and investigated as needed for 2 of 2 years from 07/30 /2024 to 06/11/2026. 2. The MA confirmed the finding above on 06/11/2026 at 11:30 am. ** Repeat Deficiency**
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation of the laboratory, record review, lack of documentation, and interview with the Medical Assistant (MA), the laboratory failed to meet applicable analytic systems requirements in 493.1251 through 493.1283 for 2 of 2 years from 07 /30/2024 to 06/11/2026. Refer to D5401, D5403, D5463
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on policy review, lack of documentation, and interview with the Medical Assistant (MA), the laboratory director (LD) failed to perform and document the required procedure review as specified per the laboratory's Policies and Procedure manual for 2 of 2 years from 07/30/2024 to 06/11/2026. Findings include: 1. On the day of the survey, 06/11/2026 at 10:00 am., review of the laboratory's policy manual revealed the laboratory's Onsite assessment by Medical Director or Designee policy stated: "The Medical Director will approve and review all procedures or policies before they are being placed in use. And review all procedures and policies every 2 years or if any changes in policies occur." 2. The LD failed to provide documentation for the policy review performed for 2 of 2 years from 07/30/2024 to 06/11/2026. 3. The laboratory performed 2,500 hematology tests in 2025 (CMS 116, estimated annual volume, dated 06/11/2026). 4. The MA confirmed the findings on 06/11/2026 at 11:45 am.
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 review of laboratory procedure manual, and interview with the Medical Assistant (MA), the laboratory failed to provide a complete procedural manual for Complete Blood Count (CBC) testing performed on the Abbott Cell-Dyn Emerald hematology analyzer for 2 of 2 years from 07/30/2024 to the date of survey. Findings include: 1. On the day of survey, 06/11/2026 at 11:15 pm, review of the laboratory's CBC procedure revealed the laboratory failed to include the following applicable requirements under 493.1251 (b) for 2 of 2 years from 07/30/2024 to 06/11/2026: - Reference intervals (normal values). - Imminently life-threatening test results, or panic or alert values. - 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. 2. The MA confirmed the above findings on 06/11/2026 at 11:45 am. ** Repeat Deficiency**
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g) (d)(7) Over time, rotate control material testing among all operators who perform the test. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interviews with the Medical Assistant (MA), the laboratory failed to rotate over time control material testing between 1 of 2 testing personnel (TP) who performed Complete Blood Count testing (CBC) on the Abbott Cell Dyn Emerald hematology analyzer from 07/30/2024 today of survey. Findings include: 1. On the date of the survey, 06/11/2026 at 10:45 am, review of the laboratory's QC records for the Cell Dyn Emerald revealed 1 of 2 TP (CMS 209 TP# 1) failed to perform QC for CBC testing from 07/30/2024 to 06/11 /2026. 2. The laboratory performed 2,500 hematology tests in 2025 (CMS 116, estimated annual volume, dated 06/11/2026). 3. . During interview on 06/11/2026 at

	11:45 am, the MA confirmed the findings above and that both TP#1 and TP #2 performed patient testing from 07/30/2024 to 06/11/2026. **Repeat Deficiency**
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 review of Patient Test Reports and interview with the Medical Assistant (MA), the laboratory failed to include on the test report the units of measurement for Complete Blood Count (CBC) testing performed from 07/30/2024 to the day of survey. Findings Include: 1. On the day of survey, 06/11/2026 at 11:30 am, review of 1 of 1 patient's test reports revealed, the reports did not list the units of measurement for CBC testing performed on 06/1/2026. 2. The laboratory performed 2,500 tests in 2025 (CMS-116, estimated annual volume, dated 06/11/2026). 3. The MA confirmed the findings above on 06/11/2026 at 11:30 am.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and interview with the Medical Assistant (MA), the laboratory failed to include pertinent reference intervals/normal values on patient test reports for 16 of 16 Complete Blood Count (CBC) analytes tested in analytes tested from 07/30/2024 to 06/11/2026. Findings Include: 1. On the day of the survey, 06/11 /2026 at 11: 45 am, review of patient reports revealed that the laboratory failed to include pertinent reference intervals/normal values on the final report for 16 of 16 CBC analytes tested from 07/30/2024 to 06/11/2026. 2. The laboratory performed 2,500 hematology tests in 2025 (CMS 116, estimated annual volume, dated 06/11 /2026). 3. The MA confirmed the findings above on 06/11/2026 at 11:50 am.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the Medical Assistant (MA), the Laboratory Director failed to provide overall management and direction of the laboratory in accordance with 493.1407 for a moderate complexity laboratory for 2 of 2 years from 07/30/2024 to 06/11/2026. Refer to D6018, D6020
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the Medical Assistant (MA), the laboratory director (LD) failed to ensure that all PT reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and identify any problems that require corrective action for 5 of 7 API PT events performed from 07/30/2024 to the day of survey. Findings include: 1. The API PT performance evaluation form stated, "the following on the proficiency testing performance evaluation form: "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. The laboratory procedure On Site Assessment by Medical Director or Designee stated, "The Medical Director or the Designee (Dr. Michael Rachshtut), will sign off on all Proficiency testing being performed, reviewing the Survey results and addressing any unsatisfactory results on the surveys." 3. On the day of survey, 06/11 /2026 at 11:00 am, review of the laboratory's API PT records revealed the LD /designee failed to provide documentation of the corrective action taken when the laboratory's reported result failed to fall within the API expected result range for the following 5 of 7 API PT events performed from 07/30/2024 to 06/11/2026:: - 2024 Hematology/Coagulation - 3rd event: Hem-09 MCV reported result 18.6, expected result 82.0-88.6 - 2025 Hematology/Coagulation - 1st event: Hem-05 MPV reported result 8.9, expected result 9.0-10.6 . - 2nd event Hem-06 Hemoglobin reported result 10.6, expected result 10.7-11.7 - 3rd event: Hem-14 MCV, reported result 19.5, expected results 90.3-97.9. - 2026 Hematology/Coagulation - 1st event: Hem-03 Hemoglobin, reported result 5.1, expected result 5.2-5.7, HEM-02 MPV, reported result 9.1, expected result 9.2-10.6, HEM-04 MPV, reported result 9.2, expected result 9.3-10.8. 4. The MA confirmed the findings above on 06/11/2026 at 11:50 am. **Repeat Deficiency**
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment 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: A. Based on review of the quality records (QC), review of the QC procedure and interview with the Medical Assistant (MA), the laboratory director failed to ensure verification of control ranges was peformed as per laboratory policy when a new lot of QC was put into use for 1 of 1 Abbott Cell Dyn Emerald hematology analyzer from 07 /30/2024 to the day of survey. Findings include: 1. The laboratory's CBC Controls - Assayed Control Hem 01 procedures stated, "Verification of Control Ranges 1. When a new of QC arrives, a sticker will be placed on the QC "NEW LOT DO NOT USE." 2. The new lot and old lot are run at the same time for all three levels (low, normal, high) at least 5 times, over a 5 day period to validate the ranges, the QC runs will be printed out and put in the "New Lot evaluation" folder. 3. The new lot and old lot parallel runs for all levels will be evaluated by the Supervisor, prior to starting any new lot of QC. If the Parallel runs are acceptable, place a "Ready to use" sticker on the boxes of the new lot of QC." 2. On the date of the survey, 06/11/2026 at 11:30 am, the laboratory failed to provide documentation of parallel lot to lot studies for each new lot of quality control put into use for 1 of 1 Abbott Cell-Dyn Emerald from 07/30 /2024 to 06/11/2026. 3. The MA confirmed the findings above on 06/11/2026 at 11:45 am. ** Repeat Deficiency** B. Based on lack of documentation and interview with the Medical Assistant (MA), the laboratory director (LD) failed to ensure that the a quality assessment policy was established to assure the quality of laboratory services provided and to identify failures in quality as they occur for 2 of 2 years 07/30/2024 to the day of survey. Findings include: 1. On the date of the survey, 06/11/2026 at 11:30 am, the laboratory failed to provide a a written policy that included the laboratories processes used to assess and assure the quality of laboratory services and identify failures in quality as they occur for 2 of 2 years from 07/30/2024 to 06/11/2026.. 2. The MA confirmed the findings above on 06/11/2026 at 11:45 am.