

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2034974	<b>(X3) Date Survey Completed</b>  12/19/2025
<b>Name of Provider or Supplier</b>  Satish A Shah Md Pllc	<b>Street Address, City, State</b>  500 Evergreen Dr, Suite G3, Glen Mills, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was conducted by the Pennsylvania State Agency at Rittenhouse Hematology & Oncology LLC Laboratory on 12/19/2025. The laboratory was found out of compliance with the following conditions: 493.801 Condition: Enrollment and testing of samples. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's Proficiency Testing (PT) policy, lack of documentation, and interview with the Laboratory supervisor (CMS 209 personnel #4, dated 12/18/2025), the laboratory failed to enroll in an HHS approved PT program for 22 of 22 months when Hematology testing was performed from 02/02/2024 to the day of survey. Findings include: 1. The laboratory's Proficiency Testing policy stated, "Currently in use is the Excel program from CAP. Surveys are received 3 times a year. They are to be rotated among all employees using the analyzer." 2. On the date of the survey, 12/19/2025, the laboratory could not provide documentation for the enrollment in an HHS approved PT program for Hematology (Complete Blood Count) examinations performed from 02/02/2024 to 12/19/2025. 3. The laboratory could not</p>

provide documentation for the verification of accuracy performed 3 times a year for Complete Blood Count examinations performed from 02/02/2024 to 12/19/2025. 4. Review of the laboratory's test logs revealed the laboratory performed 16,566 Complete Blood Count examinations from 02/02/2024 to 12/19/2025. 5. The Laboratory Supervisor (CMS 209 personnel #4, dated 12/18/2025) confirmed the above findings on 12/19/2025 at 11:11 am.

**D5407**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(d)

(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's procedures and interview with the Laboratory Supervisor (CMS 209 personnel #4, dated 12/18/2025), the laboratory failed to ensure that 1 of 1 laboratory procedure manual in use for Hematology testing was approved, signed and dated by the current Laboratory Director (LD) for 6 of 6 months from 06/01/2025 to 12/19/2025. Findings include: 1. On the day of survey 12/19/2025 at 09:33 am, review of the laboratory procedure manual in use for Hematology testing revealed the laboratory failed to ensure all procedures were approved, signed and dated by the current LD when Complete Blood Count examinations were performed for 6 of 6 months from 06/01/2025 to 12/19/2025. 2. Review of the laboratory's test logs revealed the laboratory performed 8028 Complete Blood Count examinations from 06/01/2025 to 12/19/2025. 3. The Laboratory Supervisor (CMS 209 personnel #4, dated 12/18/2025) confirmed the above findings on 12/19/2025 at 11:11 am.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's temperature records, lack of documentation, and interview with the Laboratory Supervisor (CMS 209 personnel #4, dated 12/18/2025), the laboratory failed to establish acceptable criteria for relative humidity to ensure operating conditions were met for reliable test system operation and test result reporting of complete blood count (CBC) examinations performed for 22 of 22 months from 02/02/2024 to 12/12/2025. Findings Include: 1. On the day of the survey, 12/19/2025 at 09:27 am, review of the laboratory's temperature logs revealed the laboratory failed to establish acceptable criteria for relative humidity to ensure operating conditions were met for the following instrumentation used when CBC examinations were performed from 02/02/2024 to 12/19/2025: - 1 of 1 Beckman Coulter DxH 500 hematology analyzer (manufacturer's acceptable range: maximum

80% RH) 2. The laboratory could not provide documentation for the monitoring of relative humidity for 22 of 22 months when CBC examinations were performed from 02/02/2024 to 12/19/2025. 3. Review of the laboratory's test logs revealed the laboratory performed 16,566 Complete Blood Count examinations from 02/02/2024 to 12/19/2025. 4. The Laboratory Supervisor (CMS 209 personnel #4, dated 12/18/2025) confirmed the findings above on 12/19/2025 at 11:11 am.

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(a)

(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's Quality Assurance policy, lack of documentation and interview with the Laboratory Supervisor (CMS 209 personnel #4, dated 12/18/2025), the laboratory failed to perform and document calibration procedures at least once every 6 months as required for 1 of 1 Beckman Coulter DxH 500 hematology analyzer used to perform Complete Blood Count examinations from 02/02/2024 to date of the survey. Findings include: 1. The laboratory's Quality Assurance policy stated, "Calibration will be performed every 6 months using S-CAL calibrator for routine maintenance." 2. On the day of survey, 12/19/2025, the laboratory could not provide documentation of the calibration procedures performed at least once every 6 months for Complete Blood Count examinations tested on 1 of 1 Beckman Coulter DxH 500 hematology analyzer from 02/02/2024 to 12/19/2025. 3. Review of the laboratory's test logs revealed the laboratory performed 16,566 Complete Blood Count examinations from 02/02/2024 to 12/19/2025. 4. The Laboratory Supervisor (CMS 209 personnel #4, dated 12/18/2025) confirmed the above findings on 12/19/2025 at 11:11am.

**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 observation of the laboratory, review of records, and interview with the Laboratory Supervisor (CMS 209 personnel #4, dated 12/18/2025), the Laboratory Director failed to provide overall management and direction of the laboratory in accordance with 493.1407 for 2 of 2 years when moderate complexity hematology

testing was performed in 2024 and 2025. Findings include: 1. The Laboratory Director failed to ensure established Quality Assessment programs were maintained to assure the quality of laboratory services provided. Refer to D6020. 2. The Laboratory Director failed to specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing. Refer to D6032.

**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:  
Based on review of the laboratory's Quality Assessment policy, lack of documentation and interview with the Laboratory Supervisor (CMS 209 personnel #4, dated 12/18/2025), the Laboratory Director (LD) failed to ensure established Quality Assessment (QA) programs were maintained to assure the quality of laboratory services provided when moderate complexity hematology testing was performed for 6 of 6 months from 06/01/2025 to the date of the survey. Findings include: 1. The laboratory's Quality Assessment Policy stated, "The Laboratory Manager or Laboratory Director's designee, will review the laboratory records monthly for the following quality factors: Patient Test Management, Quality Control, Proficiency Testing, Maintenance, Inventory, Communications, Complaints. The Laboratory Manager or Laboratory Director's designee, will review the quality factor ratings with the Laboratory Director. The Laboratory Director will sign and date the Monthly Quality Assessment form with the month reviewed and the date of review." 2. On the day of survey 12/19/2025 at 9:14 am, the laboratory could not provide documentation of the QA form used to assess the laboratory's pre-analytical, analytical and post-analytical processes for 6 of 6 months when Complete Blood Count examinations were performed from 06/01/2025 to 12/19/2025. 3. The Laboratory Supervisor (CMS 209 personnel #4, dated 12/18/2025) confirmed the above findings on 12/19/2025 at 11:11 am.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(14)

(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on lack of documentation and interview with the Laboratory Supervisor (CMS 209 personnel #4, dated 12/18/2025), the Laboratory Director failed to specify in writing the responsibilities and duties of 2 of 2 testing personnel (TP) involved in the pre-analytic, analytic, and post-analytic phases of moderate complexity hematology testing from 02/02/2024 to the day of survey. Findings include: 1. On the day of survey, 12/19/2025 at 9:33 am, the laboratory could not provide the written list of

responsibilities for 2 of 2 TP (TP # 1 through TP# 2, CMS-209 dated 12/18/2025) involved in the pre-analytic, analytic, and post-analytic phases of Complete Blood Count examinations performed from 02/02/2024 to 12/19/2025. 2. The laboratory could not provide documentation that identified which examinations each TP was approved to perform, and whether supervision is required for such tasks. 3. The Laboratory Supervisor (CMS 209 personnel #4, dated 12/18/2025) confirmed the above findings on 12/19/2025 at 11:11 am.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPLEXITY**  
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:  
Based on review of the CLIA Laboratory Personnel Report (Form CMS 209), competency assessment records, lack of documentation, and interview with the Laboratory Supervisor (CMS 209 personnel #4, dated 12/18/2025), the laboratory failed to ensure 1 of 2 Technical Consultants (TC) met the requirements to perform technical consultation for moderate complexity hematology testing performed in 2025. Refer to D6035

**D6035**

**TECHNICAL CONSULTANT QUALIFICATIONS**  
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and

(b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on review of the CLIA Laboratory Personnel Report (Form CMS-209), competency assessment (CA) records, lack of Personnel Qualification records, and interview with the Laboratory Supervisor (CMS 209 personnel #4, dated 12/18/2025), the laboratory failed to ensure 1 of 2 Technical Consultants (TC) met the minimum requirements of 493.1411 to perform technical consultation for moderate complexity hematology testing performed in 2025. Findings include: 1. On the day of survey, 12/19/2025 at 09:52 am, review of the CMS 209 form revealed, Personnel #4 (CMS 209, dated 12/18/2025) was listed as a TC for hematology. 2. Review of CA records revealed Personnel #4 performed the competency assessments for Complete Blood Count testing performed by Testing Personnel #1 and #2 (CMS 209 personnel #2 and #3, dated 12/18/2025) in 2025. 3. The laboratory failed to provide education credentials for 1 of 2 TC (CMS 209 personnel #4, dated 12/18/2025) who performed technical consultation for moderate complexity hematology testing (Complete Blood Count) performed in 2025. 4. The Laboratory Supervisor (CMS 209 personnel #4, dated 12/18/2025) confirmed the findings above on 12/19/2025 at 11:11 am.