Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2028285	01/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Satish A Shah Md Pllc	1 Presidential Blvd, Bala Cynwyd, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's Proficiency Testing (PT) policy, American Proficiency Institute (API) PT records and interview with the Medical Assistant (MA), the laboratory director (LD)/designee and testing personnel (TP) failed to attest to the routine integration of samples into the patient workload for 2 of 3 Hematology /Coagulation PT events performed in 2022 and 1 of 3 Hematology/Coagulation PT events performed in 2023. Findings include: 1. The laboratory's Addendum to Proficiency Testing Policy states, "Lab director will monitor all proficiency testing, scores, attestations, and events". 2. On the day of survey, 01/03/2024 at 09:30 am., review of API PT records revealed the following attestation statements were not signed by either the LD/designee or TP: -2022 Hematology/Coagulation 1st and 3rd events: Hematology -3S: Red Blood Cell (RBC) count, White Blood Cell (WBC) count differential, Platelet count, Hematocrit (%), Hemoglobin (g/dL) - 2023 Hematology/Coagulation 3rd event: Hematology -3S: Red Blood Cell (RBC) count, White Blood Cell (WBC) count differential, Platelet count, Hematocrit (%), Hemoglobin (g/dL) 3. The MA confirmed the findings above on 01/03/2024 at 11:00 am
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance

	(that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). 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 failed to verify the accuracy of the PT results obtained for 1 of 1 API Hematology/Coagulation testing events in 2023. Findings Include: 1. On the day of survey, 01/03/2024 at 09:39 am., review of the laboratory's API PT records revealed that the laboratory did not verify the accuracy for the following analyte that was not scored by the PT agency due to non-consensus: - API 2023 (2nd event): White Blood Cell Differential, Monocytes/mixed (%), HSY-07, HSY-09 2. The API Proficiency Testing performance Evaluation form states " 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.". 3. MA confirmed the findings above on 01/03/2024 at 11:00 am.
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 the review of Patient Test Reports and interview with Medical Assistant (MA), the laboratory failed to include on the test report the address of the laboratory location where Complete Blood Count (CBC) testing was performed from 04/27/2022 to the day of survey. Finding Include: 1. On the day of survey, 01/03/2024 at 10:50 am, review of 3 of 3 patient's test reports revealed, the reports did not list the exact address and location where testing was performed on 05/04/2022, 06/14/2023 and 12 /22/2023. 2. The location of the laboratory is Rittenhouse Hematology & Oncology (1 Presidential Boulevard Suite 115 Bala Cynwyd PA 19004) but Rittenhouse Hematology & Oncology (207 N Broad St. 6th floor Philadelphia, PA 19107-1500) was listed on the final reports. 3. The annual testing volume for Hematology is 1000. (CMS-116) 4. The MA confirmed the findings above on 01/03/2024 around 11:00 am.