Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0195317	08/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Satish A Shah Md Pllc	One Medical Center Boulevard, Vivacqua Pavilion, Upland, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) records and interview with the Technical Consultant (TC) (CMS 209 personnel #2), the laboratory failed to retain background count records for Sysmex XP 300 Hematology analyzer from 09/09/2021 to 07/07/2022. Findings include: 1. On the day of survey, 08/17/2023 at 11:30 am, the laboratory could not provide background count records for Complete Blood Count (CBC) examinations performed from 09/09/2021 to 07/07/2022. 2. The laboratory's annual test volume for CBC is 18,522 in 2022 (CMS 116). 3. The TC confirmed the findings above on 08/17/2023 around 12:15 pm.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii)

	Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the Technical Consultant (TC) (CMS 209 personnel #2), the laboratory failed to have the required records accessible during the course of the laboratory survey performed on 08/17/2023. Findings include: 1. On the day of survey, 08/17/2023 at 11:38 am, the laboratory could not provide the following records upon request: - Sysmex XP 300 maintenance logs from September 2021 to January 2022. 2. The TC confirmed the findings above on 08/17/2023 around 12:15 pm.