Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0895307	10/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Surinder Vohra Md Pc	1600 Sixth Avenue Suite 101, York, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 and interview with Testing Personnel #2 (TP), the laboratory failed to monitor and document room and refrigerator temperatures to ensure operating conditions were met for the proper storage of hematology reagents and ensure reliable test system operation of the Sysmex XP 300 from 01/20/2023 to 10/16/2024. Findings Include: 1. On the date of the survey, 10/16/2024 at 10:00 am, review of the laboratory's temperature control logs revealed the laboratory failed to monitor and document room temperatures (acceptable range: 15-30 degrees Celsius) and refrigerator temperatures (acceptable ranges 2-8 degrees Celsius) to ensure operating conditions for the Sysmex XP 300 were met for the following days from 01/20/2023 to 10/16/2024: - 23 of 30 days in September 2024 2. The hours of laboratory testing per the CMS 116 are Monday thru Wednesday 9:00 am to 05:00 pm. 3. TP#2 revealed during an interview, 10/17/2024 at 11:00 am, that temperatures were not monitored on weekends, holidays, and when personnel are not on site in the laboratory from 01/20/2023 to 10/16/2024.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on maintenance record review and interview with testing personnel #2 (TP), the laboratory failed to document maintenance performed on the Sysmex XP300 hematology analyzer from 2/14/2023 to 10/10/2024. Findings include: 1. On the day of the survey 10/16/2024 at 10:00 am, review of the laboratory's XP300 Maintenance Log revealed the laboratory failed to document the following maintenance performed on 1 of 1 Sysmex XP300 (B0622) from 02/14/2023 to 10/16/2024: - Daily Maintenance - Weekly Maintenance - Monthly Maintenance - Quarterly Maintenance 2. The laboratory performed 3486 complete blood cell examinations in 2024 (CMS 116 annual volume) 3. TP#2 confirmed the finding above on 10/16/2024 at 10:00 am
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (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 (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (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 record review, lack of documentation, and interview with Testing Personnel #2 (TP), the laboratory failed to perform and document calibration procedures on the Sysmex XP300 hematology analyzer in 2024. Findings include: 1. The laboratory's Accreditation/Calibrations/Proficiency policy stated, calibrations "done by Sysmex service technicians twice a year, approximately every 6 months." 2. On the day of survey, 10/16/2024, the laboratory failed to provide documentation for the calibrations performed on the Sysmex XP300 hematology analyzer in 2024. 3. TP#2 confirmed the finding above on 10/16/2024 at 11:00 am.