

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0895307	(X3) Date Survey Completed 09/23/2020
Name of Provider or Supplier Surinder Vohra Md Pc	Street Address, City, State 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory personnel interview and review of the policy & competency records, the Laboratory Director acting as Technical Consultant, failed to establish written policies and procedures to assess consultant competency for 4 of 4 Testing Personnel, from 05/09/2018 through the date of the survey. Findings: 1. The Technical Consultant failed to establish and follow written policies and procedures to assess competency for 4 of 4 Testing Personnel from 05/09/2018, through the date of the survey. 2. During the survey 10:00 09/23/2020, the Laboratory Supervisor confirmed, the above finding.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of laboratory temperature records and interview with the Laboratory Supervisor, the laboratory failed to document room temperature for the laboratory, from 05/09/2018 through the date of the survey. . Findings include: 1. The manufacturer of Sysmex hematology controls, requires a room temperature range of (15 - 30 C) to equilibrate, prior to running hematology controls. 2. Sysmex hematology controls were run each day of patient testing from 05/09/2018 through the date of the survey. 3. 3,596 Complete Blood Counts tests were performed using Sysmex hematology controls from 05/09/2018 through the date of the survey. 4. The laboratory could not provide documentation of room temperature from 05/09/2018 through the date of the survey. 5. The Laboratory Supervisor confirmed the above findings during the survey on 09/23/2020 at 10:47 hours.