

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D0164352	<b>(X3) Date Survey Completed</b> 10/28/2025
<b>Name of Provider or Supplier</b> Sullivan Internal Medical Group Pc	<b>Street Address, City, State</b> 4058 State Route 42, Suite 5, Monticello, NY	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 review of personnel training and competency assessment records, Standard Operating Procedures (SOPs), as well as interview with the Technical Consultant (TC), the laboratory failed to establish and approve written policies and procedures to assess employee and, if applicable, consultant competency. FINDINGS: 1. There was no documentation of annual Clinical Consultant (CC) and TC competency assessment performance. 2. The current, approved SOPs did not include instructions for performing such activity. 3. The TC confirmed the findings on October 28, 2025, at approximately 11:30 A.M.</p>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective</p>

action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on direct observation, review of SOPs, lack of thermometer calibration records, as well as interviews with the TC and TP (Testing Person), the laboratory failed to draft and approve procedures for thermometer calibration and certificate retention. FINDINGS: 1. There was no calibration documentation for the Temp-Chex Red Spirit Streck thermometer, lot: 12730550, utilized for monitoring the refrigerator temperature where laboratory patient testing materials, analyzer calibrator, quality controls, API PT samples, and patient specimens were stored. 2. There was no calibration certificate documentation for the Elitech GSP-6 Digital Temperature and Humidity Data Logger, SN: EFG213101396, utilized for monitoring the room temperature and humidity of the laboratory where patient testing materials were stored and patient testing performed. It was noted that the respective digital thermometer included a certificate indicating calibration expiration March 20, 2023. 3. The current, approved SOPs did not include instructions for performing such activity. 4. The TC and TP confirmed the findings on October 28, 2025, at approximately 12:50 P.M.