

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2294140	(X3) Date Survey Completed 12/09/2025
Name of Provider or Supplier Summit Rheumatology	Street Address, City, State 2451 E Baseline Rd Ste 425, Gilbert, AZ	
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
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, review of patient test results maintained in the Electronic Medical Record (EMR), and interview with the Technical Supervisor (TS-1), the laboratory failed to have a system in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (electronically transmitted) to the final report destination, in a timely manner. Findings include: 1. This laboratory began patient testing in July 2024. The laboratory utilizes the Dynex DSX Elisa Processor to perform patient testing under the subspecialties of Mycobacteriology and General Immunology with an annual reported test volume of 22,000. . 2. Patient-specific data and the final test result information for testing performed are electronically transmitted from the Dynex DSX ELISA Processor into the patient's EMR. 3. No documentation was presented for review during the survey conducted on 12/9/25 to indicate the laboratory has a system in place to ensure the accuracy of patient-specific data and patient test results that are electronically transmitted into the EMR. 4. The TS-1 interviewed on 12/9/25 at 12:30 PM confirmed the laboratory failed to have a system in place to verify the accuracy of patient-specific data and patient test results that are manually entered into the EMR.</p>