

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  64D0724937	<b>(X3) Date Survey Completed</b>  08/23/2023
<b>Name of Provider or Supplier</b>  Lbj Tropical Medical Center	<b>Street Address, City, State</b>  1234 Paul Turner Dr, Pago Pago, AS	
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>D5801</b>	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>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 a random review of patient test records and an interview with testing personnel (TP) #11 on August 23, 2023, the laboratory failed to ensure test results were accurately and reliably sent from the point of data entry (interfaced or manual entry) to final report destination in a timely manner. The laboratory reported performing approximately 10,000 general immunology tests annually. Findings: 1. Upon review of randomly selected patient test results, one of nine patient results selected was not reported from the initial instrument run to the patient's electronic medical record. 2. The patient test result selected for Hepatitis B core antibody (HBcAb) was initially tested on the Roche Cobas e 411 analyzer on February 8, 2023, and the result was positive. The laboratory protocol requires positive results for HBcAb to be retested before reporting. The sample was never retested, and a final test result was never transcribed into the patient's electronic medical record as of August 23, 2023, at 12:15 PM. 3. An interview with TP #11 on August 23, 2023, at approximately 12:15 PM confirmed that the laboratory failed to report one of nine patient test results in an accurate and timely manner.</p>