Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2032976	06/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sedona Medical Center Laboratory	3700 West State Route 89a, Sedona, 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	TEST REPORT CFR(s): 493.1291(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. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the facility personnel, the laboratory failed to have a system in place to ensure the accuracy of test results that are manually entered into the laboratory's information system (LIS). Findings include: 1. The laboratory performs patient testing in the specialties of Microbiology, Diagnostic Immunology, Chemistry, and Hematology, with an approximate annual test volume of 29,500. It is the practice of the laboratory to manually enter test results into the LIS for the following tests: Gram Stains, Blood Gas testing performed on the I-stat analyzer, Serum hCG, drug screens performed on the Medtox analyzer and urine microscopics. 2. No documentation was presented for review during the survey to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are manually entered into the LIS. 3. The facility personnel confirmed that the laboratory did not have a system in place to verify the accuracy of the patient test results that are manually entered by the testing personnel into the LIS.