

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0857715	(X3) Date Survey Completed 01/06/2025
Name of Provider or Supplier Blair S Kranson Md	Street Address, City, State 7320 Woodlake Ave Ste 395, West Hills, CA	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's preventive maintenance (PM) documentation, eight (8) randomly selected patient test records, and an interview with the office manager (OM), it was determined that the laboratory failed to ensure performed tests and function checks were documented properly prior to patient testing. The findings include: 1. Based on the review of the 8 patient test records, no corrective action was found for the two out of 8 records that were discrepant in documentation. Thus, the accuracy and quality of patient reports cannot be ascertained. a. Patient DJ serviced on April 27, 2023, had a missing entry for cryostat temperature. b. Patient LR serviced on June 20, 2024, was recorded under June 24, 2024, in the cryostat PM log. 2. The OM affirmed by interview at approximately 1:45 p.m. on January 6, 2025, that the laboratory missed checking the log sheet when quality assessment was performed as mentioned in statement #1. 3. Based on the annual testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 800 patient tests for Histopathology, including the time the missing and incorrect entries for PM occurred. Thus, the quality and accuracy of patient reports cannot be assured.</p>