

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0934287	(X3) Date Survey Completed 03/05/2025
Name of Provider or Supplier Healthcare Partners Affiliates	Street Address, City, State 18546 Roscoe Blvd Ste 300, Northridge, 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>(b)(2)(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. (b)(2)(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, five (5) 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 surveyor's review of 5 randomly selected patient test records, no corrective action was found for the three out of 5 records that lacked staining PM documentation. Thus, the accuracy and quality of patient reports from October 9, 2023, December 4, 2023, and January 29, 2024 cannot be ascertained. 2. The OM affirmed by interview at approximately 11:00 a.m. on March 5, 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 240 patient tests for Dermatopathology, including the time the missing entries for the stain PM occurred. Thus, the quality and accuracy of patient reports cannot be assured.</p>