

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2267187	(X3) Date Survey Completed 07/09/2025
Name of Provider or Supplier Corewell Health W Beaumont Univ Hosp	Street Address, City, State 3577 W 13 Mile Road Suite 101, Royal Oak, MI	
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 record review and an interview with the Technical Consultant (TC), the laboratory failed to perform and document maintenance for the hematology analyzer for 18 (August 2023 - January 2025) of 24 months reviewed. Findings include: 1. A record review of the laboratory maintenance records for the Beckman Coulter DxH 520 hematology analyzer revealed that documentation for maintenance was not present for 18 months (August 2023 - January 2025). 2. A review of the Beckman Coulter CxH 520 product manual revealed the Beckman Coulter DxH 520 hematology "... requires daily, weekly, and periodic maintenance to ensure optimal performance and accurate results." 3. An interview conducted on July 9, 2025, at 11:30 am with the Technical Consultant (TC) in which the surveyor requested the laboratory's Beckman Coulter DxH 520 maintenance records from August 2023 to July 2025 and the TC confirmed that maintenance records for the hematology analyzer were not available for the period in question.</p>