

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0668256	(X3) Date Survey Completed 05/07/2026
Name of Provider or Supplier Henry Ford Laboratory Woodhaven	Street Address, City, State 22505 Allen Road, Woodhaven, 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
D0000	An announced CLIA validation survey was conducted at Henry Ford Laboratory - Woodhaven on May 7, 2026, by a federal surveyor from the CMS CLIA Survey Branch. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be in compliance with condition-level CLIA requirements. The following standard-level deficiency was cited.
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory temperature records, review of laboratory procedures, and interview with technical consultant (TC) #1 and #2, the laboratory failed to document corrective actions for when the specimen refrigerator temperature fell outside of the acceptable range in 1 out of 28 days in November 2025. Findings: 1. The Housekeeping Procedure -temps, humidity, cleaning, and maintenance of lab equipment, page 3, under 5. If the temperature falls outside of the acceptable range: bullet point six states, "Document the problem and the corrective action taken on the log sheet". 2. Review of laboratory specimen refrigerator temperature log sheet revealed on November 28, 2025 the max temperature was at 11 degree Celsius. 3. The specimen refrigerator acceptable range was set at 2 - 8 degrees Celsius. 4. The</p>

laboratory did not document corrective action taken on the log sheet nor could the laboratory provide documentation of any corrective actions performed. 5. Interview with TC#1 and #2 on May 7, 2026 at 11:50 am confirmed that no corrective action was performed or documented for the out of range refrigerator temperature.