

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1031713	(X3) Date Survey Completed 05/13/2026
Name of Provider or Supplier Genesis Medical Laboratory	Street Address, City, State 8150 Perry Highway Suite 102, Pittsburgh, PA	
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	A routine recertification survey was conducted by the Pennsylvania State Agency at Genesis Medical Laboratory on 5/13/2026. The laboratory was found to be out of compliance with the following condition: 493.1250 Condition: Analytic systems
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation of the laboratory, lack of documentation, and interview with Technical Supervisor (TS) #1, the laboratory failed to meet the applicable analytic systems requirements in 493.1254 to assess the maintenance and function checks as defined by the manufacturer for 1 of 1 humidity monitor used to record room humidity (RH) in the laboratory when hematology, chemistry and immunology testing was performed from 6/25/2024 to 5/13/2026. Refer to D5429
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by:

Based on observation of the laboratory, lack of documentation, and interview with Technical Supervisor (TS) #1, the laboratory failed to assess the maintenance and function checks as defined by the manufacturer for 1 of 1 humidity monitor used to record room humidity (RH) in the laboratory when hematology, chemistry and immunology testing was performed from 6/25/2024 to 5/13/2026. Findings Include: 1. On the day of the survey, 5/13/2026 at 1:45 pm, observation of the laboratory revealed 1 of 1 ACURITE humidity monitor with no expiration date, serial number or identifying label on the instrument. 2. The laboratory could not provide maintenance /function check records for the 1 of 1 ACURITE humidity monitor used to record RH in the laboratory when hematology, chemistry and immunology testing was performed from 6/25/2024 to 5/13/2026. 3. TS #1 (CMS 209 personnel #2, dated 4/20/26) confirmed the above findings on 5/13/2026 at 2:15 pm. *REPEAT DEFICIENCY

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(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.

This STANDARD is not met as evidenced by:
Based on review of laboratory records, lack of documentation, and interview with Technical Supervisor (TS) #1, the laboratory failed to document the corrective action taken when room humidity (RH) readings were outside of the laboratory's established acceptable range for 14 of 20 months when hematology, chemistry and immunology testing was performed from October 2024 to May 2026. Findings include: 1. On the day of survey, 5/13/2026 at 9:21 am, review of the laboratory's Policy for Safety in the Laboratory Environment revealed, "The Testing Environment: The Analyzers operate at ambient temperature (18-30C) and 30-80% humidity, without condensation ... Adjust temperature and humidity readings that are out of range and include any remedial action on the reverse side of the Temperature/Humidity Chart." 2. Review of the laboratory's Temperature/Humidity charts revealed RH readings were not within the laboratory's acceptable range (30 to 80% humidity) for the following 14 of 20 months when hematology, chemistry and immunology testing was performed from October 2024 to May 2026: 2024 - October: 1 of 23 days (24% RH) - November: 2 of 19 days (21% RH to 24% RH) - December: 12 of 21 days (16% RH to 24% RH) 2025 - January: 21 of 21 days (16% RH to 24% RH) - February: 15 of 20 days (16% RH to 24% RH) - March: 15 of 21 days (16% RH to 24% RH) - April: 4 of 21 days (21%RH to 24% RH) - October: 2 of 23 days (22%RH to 24% RH) - November: 10 of 18 days (21% RH to 24% RH) - December: 19 of 22 days (16% RH to 21% RH) 2026 - January: 17 of 20 days (16% RH to 24% RH) - February: 17 of 20 days (16% RH to 24% RH) - March: 6 of 21 days (16% RH to 21% RH) - May: 1 of 9 days (21%RH) 3. The laboratory could not provide documentation of remedial actions taken when RH readings were not within the laboratory's established acceptable range from October 2024 to May 2026. 4. The laboratory performed 26,902 hematology tests, 82,304 chemistry tests and 412 immunology tests in 2025 (CMS 116 estimated annual test

volume, dated 4/20/26). 5. TS #1 (CMS 209 personnel #2, dated 4/20/26) confirmed the above findings on 5/13/2026 at 2:15 pm.