Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0999920	06/10/2026
Name of Provider or Supplier	**Street Address, City, State**	
Genesis Medical Laboratory	6504 Nw 77 Ct, Miami, FL	

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 recertification survey was conducted at GENESIS MEDICAL LABORATORY from 06/08/2026 to 06/10/2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
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 record review and staff interview, the laboratory failed to document corrective actions taken when Incubator's #1 and #2 temperatures were not recorded for established operating parameters in the Microbiology laboratory area from July 1 to July 16 of 2024. Findings included: 1- Review of the TEMPERATURE LOG for incubators #1 and #2 in the area of Microbiology revealed a check mark as temperature for the testing dates 07/01/2024, 07/02/2024, 07/03/2024, 07/04/2024, 07/05/2024, 07/06/2024, 07/08/2024, 07/09/2024, 07/10/2024, 07/11/2024, 07/12/2024, 07/13/2024, 07/15/2024 and 07/16/2024. 2- Review of procedure Quality Assurance Plan GEN-030 stated in Corrective Action section 11. "Monthly audits of the records to ensure corrective actions were performed and documented for all conditions..." 3- Review of procedure Urine Culture MIC-003 signed by Laboratory Director 10/03/2025, implemented on 03/16/2020 stated in section 9. QUALITY CONTROL AND

	QUALITY ASSURANCE table for QC Item: Incubator Temperature; Frequency Requirements: Each day of use verify 35-37 C acceptable range of laboratory defined range; Documentation: Temperature Log." 4- Review of the worklist and interview with the General Supervisor at approximately 3:40 PM confirmed that 356 cases were reported out of the laboratory from July 1 to July 16 of 2024. 5- Interview on 06/10 /2026 at 4:45 PM with the General Supervisor stated that the incubators were replaced and no corrective action was recorded to refer to the previous log.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory report failed to list the laboratory name and address for the Cytology test listed in the report from 01/12/2026 to 06/08/2026, the laboratory released 131 patients reports with Cytology results in this period. Findings included: 1-Review of "NOTICE OF TEMPORARY CLOSURE OF CYTOLOGY SERVICES", signed by the Laboratory Director on 01/08/2026, revealed that the laboratory started sending out the Cytology samples received to another laboratory with effective date 01/12/2026. 2-Review of two patient reports: Patient #1 (reported date 04/30/2026) and Patient #2 (reported date 05/05/2026), revealed that two out of two reports had a result for Cytology. Both reports failed to list the name and address of the laboratory that performed the test. 3-During an interview on 06/10/2026 at 4:45 PM, the laboratory General Supervisor confirmed that the laboratory failed to list the name and address of the laboratory that performed the test for 131 patient reports with Cytology results from 01/12/2026 to 06/08/2026.