Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0999920	05/31/2024
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	A recertification survey conducted from 05/07/2024 to 05/31/2024 found GENESIS MEDICAL LABORATORY not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Condition was cited: -D6168 Testing Personnel 493.1487
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to examine Proficiency Testing samples in the same manner as patient testing with personnel who routinely perform the testing in the laboratory. Findings included: 1- Personnel records reviewed revealed that in the Microbiology section there were three testing person TP#2, TP#3 and TP#5 (as per 209 Form). 2- Review of Attestations for Microbiology 2022 revealed that TP#2: signed 1st event on 02/25/2022, 2nd event on 06/28/2022 and 3rd event 2022 (no date record). There were no attestation signature records for TP#3 and TP#5 for year 2022. During an interview on 05/10/2024 at 1:30 PM, the General Supervisor confirmed that attestation on 2022 for the Microbiology specialty were signed by TP#2.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have a signed attestation for Proficiency Testing for Microbiology/Molecular for two events (2nd and 3rd) out of three events in 2023 by the Testing Person. Findings included: 1- Review of Attestation for 2023 Second event of Microbiology revealed that the Testing Person, who performed tests for Human Papillomavirus (HPV), Chlamydia Trachomatis (CT), Neisseria Gonorrhea (NG) and Respiratory Panel with SARS-CoV-2 liquid molecular failed to sign attestation. 2- No record found for attestation for 2023 Microbiology 3rd Event for molecular tests: HPV, CT, NG, Respiratory Panel, Urinary Tract Infection (UTI) and SARS-CoV-2 liquid. 3- Interview on 05/08/2023 at 5:00 PM, the laboratory manager stated, "all attestations are signed on survey submit date.", she confirmed that the records of reference were not found during the inspection.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory had REMEL XLD Agar plate in use and expired since 04/30/2024. Based on observation, record review and interview the laboratory used Complete Blood Cell (CBC) Controls after the expiration date on 05/04/2024 as per manufacturer instructions. Findings included: - During the laboratory tour on 05/07/2024 at 9:30 AM, the surveyor observed that the laboratory was using a REMEL AGAR PLATE with Lot number 802134 expired since 04/30/2024. The laboratory tested two patients with the expired plate for stool culture. -During the laboratory tour on 05/07/2024 at 9:40 AM, the surveyor observed that the laboratory had in use the CBC controls with Lot number 123175400, 133185400 and 143195400 in the CBC Beckman DXH900 analyzer, the vials in use were opened on 04/19/2024. Based on manufacturer instructions the controls are stable after opening for 16 days (05/04/2024), the laboratory tested 90 patients on 05 /06/2024 using the CBC controls expired. During an interview on 05/07/2024 at 10:30 AM the laboratory manager confirmed that the laboratory used the expired culture plate and the CBC controls listed above.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by:

	Based on record review and interview, the laboratory failed to identify the personnel performing the testing in the final report for 5 out of 5 patients reports reviewed. Findings included: A random review of 5 patients reports dated: 10/27/2022 (patient#1), 03/31/2023 (patient#2), 10/02/2023 (patient#3), 04/05/2024 (patient#4) and 04/11/2024 (patient#5) revealed they did not have any indication of who performed the testing. During an interview on 05/10/2024 at 02:30 PM, the laboratory manager confirmed that the final reports failed to document who performed the test.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, Testing Person #1 performed proficiency testing for Huma Papillomavirus, Chlamydia Trachomatis and Neisseria Gonorrhea in 2022 and 2023 without having the Microbiology Specialty in the State of Florida Laboratory Personnel License. Refer to D6170.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on record review and interview, Testing Person(TP)#1 performed proficiency testing (PT) for Human Papillomavirus Virus (HPV), Chlamydia Trachomatis (CT) and Neisseria Gonorrhea (NG) in 2022 and 2023 without having the Microbiology Specialty in the State of Florida Laboratory Personnel License. Findings included: -Review of personnel records for TP#1 revealed that he had a Cytology Supervisor License since 01/17/1984, he failed to have the Microbiology specialty. -Review of PT records for 2022 and 2023 for Microbiology Specialty revealed the following: a) 06 /28/20222: TP#1 signed attestation for Microbiology 2nd event. b) 09/29/2022: TP#1 signed attestation for Microbiology 3rd event for the tests for CT/NG and HPV. Instrument prints out for Cobas 4800 with date 09/23/2022 listed TP#1 as the operator and the person that accepted the results for HPV on the day the PT samples were included in the worklist. c) 02/14/2023: Instrument printout for Cobas 4800 listed TP#1 as the operator and the PT samples for CT/NG first event were listed. d) 02/16 /2023: Instrument printout for Cobas 4800 listed TP#1 as the operator and the PT samples for HPV first event were listed e) 06/25/2023: Attestation signed by TP#1 and listed CT/NG as samples tested. During an interview on 05/10/2024 at 2:30 PM, the General Supervisor confirmed the findings and she explained that the Molecular Supervisor for the period of reference is no longer with the laboratory and she was the person managing the area.