

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0465828	(X3) Date Survey Completed 07/14/2026
Name of Provider or Supplier Genesis Cancer And Blood Institute	Street Address, City, State 133 Harmony Park Circle, Hot Springs, AR	
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (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 review of the CMS-209 forms, review of proficiency test attestations for 2024 through 2026, and interviews with laboratory staff, proficiency test samples were not tested by all personnel who routinely perform patient testing. Survey findings include: A. The CMS-209 forms signed 07/09/26 included nine full time testing personnel (listed as Testing Personnel [TP] TP-1 through TP-9). B. A review of proficiency test attestations for 2024 through 2026 revealed that only two testing personnel had signed proficiency attestation statements for all Hematology / Coagulation testing 2024, 2025, and 2026. C. In an interview, at 2:47 p.m. on 07/14 /2026 Technical Consultant (as listed on the form CMS-209) confirmed that TP-3, TP-4, TP-5, TP-6, TP-7, TP-8 and TP-9 (as listed on the CMS-209 form) routinely test patient samples but have not participated in proficiency testing.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test

reports.

This STANDARD is not met as evidenced by:

Based upon observation, review of temperature records, lack of documentation and interview, the laboratory failed to monitor the temperature on each day of operation in one of three rooms in which supplies with storage temperature requirements were stored. Findings follow: A) During a tour of the laboratory on 07/14/2026 at 02:47 p.m. the surveyor observed three rooms (core laboratory, phlebotomy area, and injection room) separated by closable doors. Each room contained laboratory items with a temperature storage requirement. B) A review of the laboratory's temperature records revealed that no room temperatures were presented for the injection room for the year 2024, 2025, and 2026. C) During a tour of the laboratory on 07/14/2026 at 02:47 p.m. the surveyor observed 100 Vacuette 2ml Na Citrate Blue Top blood collection tubes lot # 2507339 expiration date 2026-07-01 with a storage temperature requirement of 4- 25 degrees C and 9 BD Vacutainer Round Plastic UA Preservative Tube, Yellow, lot # 6013826 expiration date 2027-01-31 with a storage temperature requirement of 4 - 25 degrees C in the injection room. D) Upon request, the laboratory could not present the temperature records for the injection room in which the supplies identified above were stored. E) In an interview on 7/14/2026 at 03:15 p.m., the technical consultant (listed on form CMS 209) confirmed that temperature records for the injection room were not recorded.