Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0164367	03/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Garnet Health Medical Center	8881 Rte 97, Callicoon, NY	

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 exempt-state validation survey was conducted at Garnet Health Medical Center - Catskills Grover Hermannon March 18, 2024 by the CMS New York CLIA Branch Location federal surveyor. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory is in compliance with condition-level CLIA requirements. The following standard-level deficiencies were found during CLIA exempt-state validation survey performed on March 18, 2024.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 on the lack of laboratory humidity records, review of instrument instruction manual and interview with general supervisor (GS), the laboratory failed to document relative humidity conditions in the laboratory from March 2022 to March 2024. Finding Include: 1. The Gem3500 instruction manual stated an ambient environmental Requirement of 5% to 90% relative humidity. 2. The Path Fast instruction manual stated Environmental conditions: 20 - 80% relative humidity. 3. On the day of survey, March 18, 2024, a review of a sampling of instrument instruction manuals revealed the above Environmental conditions for relative humidity. 4. The laboratory could not provide documentation of humidity conditions monitored in the laboratory from 2022 to 2024. 5. On March 18, 2024 at 1:30 PM, the GS confirmed relative humidity conditions were not monitored or documented in the laboratory from 2022 to 2024.

D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of microscopic urinalysis examination quality control (QC) records, Siemens urine controls package insert and interview with General supervisor (GS), the laboratory failed to perform a positive control for cast and crystals urine sediment microscopic examination from March 2022 to March 2024. Findings Include: 1. The Siemens urine controls Level 1 and Level 2 for cast and crystals as absent or as absent - occasionally present. 2. On the day of survey, March 18, 2024, review of urine sediment microscopic examination QC records revealed, microscopic urinalysis QC records for urine controls Level 1 and Level 2 for cast and crystals were documented as absent when performed for daily QC in 2022 and 2023. 3. The GS stated approximately 350 urine sediment microscopic urinalysis are performed annually. 4. The GS confirmed on March 18, 2024 at 1:00 PM, that a positive control for cast and crystals microscopic urinalysis was not performed from March 2022 to March 2024.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of laboratory personnel competency assessment records and interview with the general supervisor (GS), the laboratory director failed to assess the competency of 1 of 1 GS for their supervisory roles in 2023. Findings Include: 1. On the day of survey, March 18, 2024, the GS could not provide a GS competency assessment performed for their supervisory roles at the Callicoon laboratory in 2023. 2. On March 18, 2024 at 11:30 am, the GS confirmed the provided GS competency from 2023 was for the Harris laboratory not the Callicoon laboratory.