Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0694769	07/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Gh Bendheim Laboratory	77 Lafayette Pl, Ste 202-A, Greenwich, CT	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow their established policies and procedures and document corrective action when the laboratory's humidity level was outside of the acceptable range in the specialty of Hematology. Findings include: 1) Record review on 7/24/2025 of the laboratory's 'Aeroscout Monitoring System' log revealed the following: a) Acceptable laboratory humidity range is 20 to 85%. b) Lack of documentation of corrective action when the humidity level was outside of the acceptable range listed in 1(a) above for 41 out of 62 working days from December 2024 through February 2025. 2) Record review on 07/24/2025 of the laboratory's 'Aeroscout Temperature & Pager Monitoring System' standard operating procedure revealed, when the temperature or humidity is outside of the designated acceptable range, an Aeroscout alert will be sent by various methods including email, page and the instant notifier. Laboratory staff is required to investigate or notify the responsible department and document corrective action directly into Aeroscout. 3) Staff interview on 07/24/2025 at 11:45 AM with the laboratory general supervisor (GS) confirmed the above findings. The GS further stated no alerts were sent from Aeroscout when humidity level was out of acceptable range. 4) The laboratory performs 6,921 complete blood counts in the specialty of Hematology.
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 implement any corrective action(s) to prevent recurrence when humidity was outside of the acceptable range in the specialty of Hematology. 1) Record review on 7/24/2025 of the laboratory's 'Aeroscout Monitoring System' log revealed the following: a. Acceptable laboratory humidity range is 20 to 85%. b. Lack of documentation of corrective action when the humidity level was outside of the acceptable range listed in 1(a) above for 41 out of 62 working days from December 2024 through February 2025. 2) Staff interview on 07/24/2025 at 11:45 AM with the laboratory general supervisor confirmed the above findings. 3) The laboratory performs 6,921 complete blood counts in the specialty of hematology