Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0970241	04/23/2025
Name of Provider or Supplier	**Street Address, City, State**	
Lehigh Valley Hospital Hla Laboratory	1200 South Cedar Crest Boulevard, Allentown, PA	

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 federal surveyors from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted an announced CLIA validation survey at the Lehigh Valley Hospital HLA Laboratory on April 23, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be in compliance with condition-level CLIA requirements. The following standard-level deficiency was found during the CLIA validation survey that concluded on April 23, 2025, at 2:00 pm. Key: Human Leukocyte Antigens = HLA.
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 on the observation of the HLA laboratory, review of instrument manufacturer documents, and interview with the general supervisor (GS), the laboratory failed to monitor humidity conditions for eight of eight instruments in use in the HLA laboratory. Findings Included: 1. Observation of the HLA laboratory on April 23, 2025 at 9:00 am, revealed the laboratory used the following instruments: a. Two Luminex FM3D instrument systems. b. Two Illumina iseq 100 sequencing systems. c. Two Beckmen Coulter Cytoflex Flow Cytometers. d. Two Applied Biosystems 2720 thermocycler. 2. Review of the following manufacturer manuals, guides, and instructions revealed: a. The Luminex FM3D instrument system User manual,

	Environmental Conditions stated, "Shipping and Operating relative humidity: 20% to 80%, non-condensing". b. The Illumina iseq 100 sequencing system, specification sheet, Operating environment stated, "Humidity: noncondensing 20%-80% relative humidity". c. The Beckmen Coulter Cytoflex Flow Cytometer Instructions for use, Temperature and Humidity stated, "Relative humidity: 15% RH-80% RH, non-condensing". d. The Applied Biosystems 2720 thermocycler user guide, Laboratory Environmental Requirements, under Temperature, Humidity, and Environment stated, "IMPORTANT..... Cycler will operate safely when the ambient temperature is 5 C to 40 C (41 F to 104 F) and will meet performance specifications when the ambient temperature is 15 C to 30 C and the ambient relative humidity is 20 to 80%". 3. The laboratory could not provide documentation for monitored humidity conditions in HLA laboratory. 4. By interview, the GS confirmed on April 23, 2025, at 12:00 pm, that humidity conditions were not monitored in the HLA laboratory. Key: Human Leukocyte Antigens = HLA. Degrees Celsius = C. Degrees Fahrenheit = F.