

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0941419	(X3) Date Survey Completed 09/17/2026
Name of Provider or Supplier Histocompatibility And Immunogenetics Laboratory	Street Address, City, State 111 S 11th St Room 8245 Gibbon Bldg, Philadelphia, 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	An on-site validation survey was completed on September 17, 2026, with the following standard-level deficiencies cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on a lack of procedures, a review of records, and interviews with general supervisors (GS) #1, #2, and #3, the laboratory failed to establish policies and procedures for Human Leukocyte Antigen (HLA) patient specimen collection, storage, and transport conditions for 2 of 2 years. Findings: 1. In the laboratory, patient specimens were received and transported to the laboratory via carrier services for HLA testing. 2. The laboratory could not provide written laboratory procedures for the collection, storage, and conditions for transport of patient specimens. 3. In an interview on September 17, 2026, at 12:00 pm, GS #1, #2, and #3 confirmed the above findings. 4. The laboratory performs approximately 26,616 HLA tests annually.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) (d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified

	in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on a lack of procedures and interviews with general supervisors (GS) #1, #2, and #3, the laboratory failed to establish written instructions for the referral specimen received in the Human Leukocyte Antigen (HLA) laboratory from 2024 to 2026. Findings: 1. In the laboratory, patient specimens were received and transported to the laboratory via carrier services for HLA testing. 2. The laboratory failed to establish a client service manual for when referral specimens were received in the HLA laboratory from 2024 to 2026. 3. In an interview on September 17, 2026, at 12:00 pm, GS #1, #2, and #3 confirmed the above findings. 4. The laboratory performs approximately 26,616 HLA tests annually.
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 observations of the HLA laboratory testing rooms, review of manufacturer instructions, review of humidity logs, and interviews with general supervisors (GS) #1, #2, and #3, the laboratory failed to establish a humidity reference range for 2 of 2 rooms where Human Leukocyte Antigen (HLA) testing was performed from 2024 to 2026. Findings: 1. Observation of two of the HLA laboratory testing rooms on September 17, 2026, at 10:00 am revealed the following test systems in use for HLA testing: a. Two BD FACslyric system flow cytometers. b. Two - Illumina Miniseq. c. Two - Luminex FLEXMAP 3D Systems. d. One - Applied Biosystems Quant Studio 6 Pro real-time PCR system. 2. Review of the following manufacturer's instructions revealed the following humidity requirements: a. BD FACSLyric System manufacturer's instruction under - Technical Specifications, "Humidity 15% to 85% relative humidity (noncondensing)". b. Illumina Miniseq manufacturer's instructions, under MiniSeq System specifications, operating environment, state: "Humidity: noncondensing 20%-80% relative humidity." c. Luminex FLEXMAP 3D Systems Specifications, general, Stated, "operating humidity 20% to 80%, non-condensing." d. Applied Biosystems Quant Studio 6 Pro real-time PCR system, Environmental requirements, Condition Humidity (instrument and computer), stated "Operation: 15% -80% (noncondensing)." 3. Review of the laboratory humidity tracking system revealed that the laboratory did not establish reference ranges for the humidity monitored in both of the laboratory testing areas. 4. In an interview on September 17, 2026, at 12:00 pm, GS #1, #2, and #3 confirmed the above findings. 5. The laboratory performs approximately 26,616 HLA tests annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observations of the Human Leukocyte Antigen (HLA) laboratory and interviews with general supervisors (GS) #1, #2, and #3, the laboratory failed to label 1 of 1 saline aliquots with preparation and expiration dates and other pertinent information. Findings: 1. An observation of the laboratory on September 17, 2026, at 10:15 am revealed one bottle of saline on the laboratory tabletop with no preparation, expiration dates, or other pertinent information. 2. The GSs stated that the saline is made daily, but were unable to provide documentation for daily preparation. 3. In an interview on September 17, 2026, at 12:00 pm, GS #1, #2, and #3 confirmed the above findings. 4. The laboratory performs approximately 26,616 HLA tests annually.