

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0644577	(X3) Date Survey Completed 07/24/2025
Name of Provider or Supplier Transplant Immunology Laboratory	Street Address, City, State Hartford Hospital 80 Seymour Street, Hartford, 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
D0000	A validation survey was conducted on 07/24/2025 and standard level deficiencies were cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, direct observation, and interview with testing person-6 (TP-6), the laboratory failed to define a refrigerated temperature range where 27 of 27 patient deoxyribonucleic acid (DNA) samples were stored. Findings included: 1. Review of the laboratory's "Specimen Requirements and Retention" stated, "1. DNA (extracted from whole blood, lymph node, or spleen) for HLA Typing a. File sample in a box labeled 'DNA' with sample date range b. Store at refrigerated temperature for up to 30 days post-testing, and -20C of below indefinitely." The procedure did not include a defined temperature range of "refrigerated." 2. During a tour of the polymerase chain reaction (PCR) room on 07/24/2025 at 2:48 PM, a small "SUMMIT" refrigerator was observed that included 27 patient DNA samples (collected from 07/16/2025 through 07/23/2025) for Human Leukocyte Antigen (HLA) typing. The refrigerator included a digital thermometer but</p>

the temperatures were not recorded. 3. During an interview on 07/24/2025 at 4:00 PM, TP-6 (per the Form CMS-209) confirmed a refrigerated temperature range, where patient DNA samples were stored, was not defined in the procedure.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions, direct observation, interview with TP-6 the laboratory failed to ensure expired Beckman-Coulter Aperture Instrument Concentration Control was not used for 27 of 27 days in 2025. Findings included: 1. Review of Beckman-Coulter Aperture Instrument Concentration Control manufacturer's instructions stated, "Opened vials are stable for 30 days when stored at 2-8C." 2. During a tour of the flow cytometry room on 07/24/2025 at 3:12 PM, an opened vial of Beckman-Coulter Aperture Instrument Concentration Control was observed (lot # 7497093, expiration date 12/20/2025) in "114 fridge." The opened date was "5-2-25" (30 day expiration was 06/01/2025). 3. During an interview on 07/24/2024 at 3:12 PM, TP-6 confirmed the observed Beckman-Coulter Aperture Instrument Concentration Control was currently in-use for the Beckman Coulter Z2 cell counter. 4. Review of "Beckman-Coulter Z2 Daily Use Quality Control" records included 27 days when the expired control (lot # 7497093, expiration date 12/20/2025) was used. The following was a random sampling of the total of 27 days: 06/02/2025 06/03/2025 06/06/2025 06/09/2025 06/10/2025 07/01/2025 07/02/2025 07/03/2025 07/06/2025 07/07/2025

D5729

HISTOCOMPATIBILITY
CFR(s): 493.1278(a)(1)(g)

(a) General. The laboratory must meet the following requirements. (a)(1) Use a continuous monitoring system and alert system to monitor the storage temperature of specimens (donor and recipient) and reagents and notify laboratory personnel when temperature limits are exceeded.

This STANDARD is not met as evidenced by:

Based on direct observation, interview with TP-6, and review of the laboratory's procedure, the laboratory failed to include a continuous temperature monitoring and alert system for a refrigerator with 27 of 27 patient deoxyribonucleic acid (DNA) samples. Findings included: 1. During a tour of the polymerase chain reaction (PCR) room on 07/24/2025 at 2:48 PM, a small "SUMMIT" refrigerator was observed that included 27 patient DNA samples (collected from 07/16/2025 through 07/23/2025) for Human Leukocyte Antigen (HLA) typing. The refrigerator included a digital thermometer but the temperatures were not recorded and was not connected to an alert system. 2. During an interview on 07/24/2025 at 2:48 PM, TP-6 confirmed the refrigerator was not part of the continuous temperature monitoring and alert system (Rees Scientific). TP-6 stated the DNA samples were retained in that refrigerator for 30 days post-testing. 3. Review of the laboratory's "Specimen Requirements and Retention" stated, "1. DNA (extracted from whole blood, lymph node, or spleen) for

HLA Typing a. File sample in a box labeled 'DNA' with sample date range b. Store at refrigerated temperature for up to 30 days post-testing, and -20C or below indefinitely." The procedure did not include a defined temperature range of "refrigerated."