

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0659038	(X3) Date Survey Completed 10/23/2025
Name of Provider or Supplier Dci Laboratory	Street Address, City, State 1616 Hayes Street, Nashville, TN	
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	During an on-site complaint survey completed on October 23, 2025, the laboratory was out of compliance with the following conditions, resulting in immediate jeopardy. 493.1290 Condition: Postanalytic Systems 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
D5800	<p>POSTANALYTIC SYSTEMS CFR(s): 493.1290</p> <p>Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's procedures, corrective action records, patient test records, and staff interviews, the laboratory failed to identify clerical errors in patient human leukocyte antigen (HLA) test results entered in the United Network for Organ Sharing (UNOS) electronic data system (UNET) during the review processes in place in August, September, and October 2025. (Refer to D5893).</p>
D5893	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c)</p> <p>(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.</p>

This STANDARD is not met as evidenced by:
 Based on a review of the laboratory's procedures, corrective action records, patient test records, and staff interviews, the laboratory failed to identify clerical errors in patient HLA test results entered in UNET during the review processes in place in August, September, and October 2025. The findings include: 1. A review of the laboratory's procedures titled "Quality Assurance" in the "Post Analytical" section, number three, "Client notification" revealed that "Before clients are notified of results (prior to result release), all results are reviewed and interpreted by testing personnel and a minimum of three senior reviewers (supervisors and/or director)." 2. A review of a corrective action report dated 10/14/2025 for patient 132107 revealed the following: The testing personnel entered unacceptable antigens in the UNET database as DR4, DR5, DR6, DR7, DR8, and DR9. The correct unacceptable antigens were DQ4, DQ5, DQ6, DQ7, DQ8, and DQ9. Two subsequent reviews did not identify the error. A virtual crossmatch performed on 10/11/2025 by the laboratory director also did not identify the clerical error, which resulted in the patient receiving an HLA incompatible organ transplant on 10/11/2025. 3. A review of patient 132107 test records revealed the following: HLA Typing Report with a comment "HLA typing entered from LIS record; sample date= 9/8/2020" reviewed by the general supervisor (GS-2) on 06/19/2025 with the following identified antigens: DRB1 17, DRB1 7, DRB3 52, and DRB4 53 HLA Typing Report PRA Results: "Serum Status 1st" HLA Class II Antibody ID-Luminex Single Antigen Panel-139 PRA Specificity: anti-DQB1=4, 5, 6, 7, 8, 9. Final review on 06/22/2025 by the laboratory director. "Serum Status 2nd" HLA Class II Antibody ID-Luminex Single Antigen Panel-139 PRA Specificity: anti DQB1=4, 5, 6, 7, 8, 9. Final review on 09/23/2025 by the GS-1. "Serum Status 3rd" HLA Class II Antibody ID-Luminex Single Antigen Panel-139 PRA Specificity: anti-DQB1=4, 5, 6, 7, 8, 9. Final review on 10/13/2025 by the GS-1. UNET electronic data entry report was reviewed by testing person four (TP-4) on 08/25/2025: "Unacceptable antigens" section DR 4, 5, 6, 7, 8, and 9. UNOS electronic "Candidate Status History" audit log report revealed actions by TP-4 on 08/25/2025 and GS-1 on 09/23/2025. HLA Typing Report Allo Crossmatch Results Flow Cytometry Crossmatch (T & B Cell) with donor and recipient samples ordered on 10/13/2025 was Flow B Cell IgG Positive with comments High levels of Donor Specific Antibodies against DQ5 and DQ6 (MFI >20,000). Enhanced therapeutic intervention is warranted to prevent anamnestic response. This donor has 13 Class II antibody verified epitope mismatches (3 DRB/ 8 DQB1/ 2 DQA1/ 0 DPB1/ 0 DPA1)." 4. The findings were confirmed in an interview with the laboratory director and TP-4 on 10/22/2025 at 4:24 p.m. Word Key: ID- Identification PRA- Panel Reactive Antibody IgG- Immunoglobulin G MFI- Mean Fluorescence Intensity DR- HLA Class II histocompatibility locus DQ- HLA Class II histocompatibility locus DP- HLA Class II histocompatibility locus

D6076

LABORATORY DIRECTOR
 CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
 Based on a review of laboratory procedures, patient test records, personnel records,

and staff interviews, the laboratory director failed to ensure that the laboratory reported accurate patient test results (Refer to D6103) and failed to ensure that the established quality assessment procedure identified failures in quality as they occurred in 2025 (three of three months reviewed) (Refer to D6093).

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on a review of laboratory procedures, patient test records, and staff interviews, the laboratory director failed to ensure that the quality assessment procedure identified errors in patient test reports as they occurred when clerical errors were present in the UNET database for one patient activation report with results reported in August, September, and October 2025. (Refer to D5893) The findings include: 1. A review of the laboratory's procedures titled "Quality Assurance" in the "Post Analytical" section, number three, "Client notification" revealed "Before clients are notified of results (prior to result release), all results are reviewed interpreted by testing personnel and a minimum of three senior reviewers (supervisors and/or director)." 2. A review of patient test records for patient 132107 revealed unacceptable donor antigens entered in the UNET database on 08/25/2025 did not match the laboratory HLA test reports in the laboratory's electronic medical record (DATALINK) for the patient antibodies that were reviewed by TP-4 (08/25/2025), GS-1 (09/23/2025 and 10/13/2025), and the laboratory director (10/11/2025). 3. The survey findings were confirmed in an interview with the laboratory director, GS-1, and GS-2 on 10/23/2025 at 12:30 p.m.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on a review of laboratory procedures, personnel records, patient records, and staff interviews, the laboratory director failed to ensure that the established policies and procedures for individuals who conduct postanalytical phases of testing, identified the need for remedial training for one (of seventeen) testing personnel (TP) (TP-4) and one (of three) general supervisors (GS) (GS-1) in August, September, and October 2025. The findings include: 1. A review of the laboratory procedure manual revealed the following: Procedure titled "Procedure: Final Review Procedure": "In order to become proficient in any area, an individual must gain experience in theoretical, technical, trouble shooting, and analytical components of each assay, in addition to accumulating a wide and detailed knowledge of our clinical pathways, the HLA system, its complexity, significance, inheritance and correlation with transplant

outcomes." "The training is therefore divided into the following sections- the ABO system, Antibody Analysis, Crossmatch Interpretation, Engraftment monitoring, HLA Typing, Post-Transplant Monitoring, and Report Review." "Therefore, a significant interval is often observed between the date a concept is discussed and the date an individual attains the necessary skill set to be deemed competent." Procedure titled "Quality Assurance": Pre-Analytical "Objectives" section: "3. To ensure key personnel are identified and laboratory staff are competent to perform all assigned /required testing." Post-Analytical "Objectives" section: "8. To provide guidelines for monitoring/assessing post-analytic system processes, and when indicated, correct identified problems." Post-Analytical "6. Post-Analytical Quality Assessment" "The effectiveness of post-analytic system monitoring is evaluated monthly and daily in certain instances (result review). If and when appropriate, corrective actions will be taken." 2. A review of the laboratory personnel records revealed the following: TP-4: "Procedure: Final Review Procedure" document in the section "2. Activations" listed "1. Understand the demographic details required for completing each activation and recognize potential issues.", "2. Understand the requirements and appropriate level of resolution for HLA typing entry.", "3. Understand the organ specific requirements for unacceptable antigen entry.", and "4. Understand the requirements for documentation." The document was dated 08/19/2025 in the "Date Discussed" box, dated 08/25/2025 in the "Reviewed Proficiently" box, and signed by TP-5 in the "Trainer Signature" box. GS-1: "2023-2024 Annual Competency Evaluation-Clinical Supervisor" was completed on 12/10/2024 by the laboratory director, which included post-analytical components: Reporting in Datalink (accurate & complete), Verification of Deceased Donor HLA typing in UNET, Entry and verification of Recipient HLA typing/antibodies in UNET, Preparation of corrective action forms or reporting errors, Review, entry, and verification of PT results (ASHI, CAP, UCLA). 3. A review of patient test records for patient 132107 revealed unacceptable donor antigens entered in the UNET electronic database on 08/25/2025 did not match the laboratory HLA test reports in DATALINK for the patient recipient antibodies that were reviewed by TP-4 (08/25/2025), GS-1 (09/23/2025 and 10/13/2025), and the laboratory director (10/11/2025). 4. The survey findings were confirmed in an interview with the laboratory director, GS-1, and GS-2 on 10/23/2025 at 12:30 p.m. Word Key: PT- Proficiency Testing ASHI- American Society for Histocompatibility and Immunogenetics CAP- College of American Pathologists UCLA- University of California, Los Angeles Health International Cell Exchange