Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0662289	04/20/2026
Name of Provider or Supplier	**Street Address, City, State**	
Dept Of Transfusion Medicine/Nih Clinical Center	10 Center Drive, Bethesda, MD	

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 conducted on April 20, 2026 with the following standard level deficiencies cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Centers for Medicare and Medicaid Service (CMS) Form 209, policies and procedures, consultant competency records, and interview with the General Supervisor (GS), the laboratory failed to establish and follow written policies and procedures to assess competency for 3 of 3 Technical Supervisors (TS) and Clinical Consultants (CC) in 2024 and 2025. Findings Included: 1) Review of the laboratory's CMS Form 209 revealed 2 TSs and 1 CC listed. 2) An established laboratory policy for consultant competency could not be provided to cover the years 2024 and 2025. 3) Review of the laboratory's competency records revealed missing competencies for the CC as well as TS#1 and TS#2. 4) In an interview on 4/20/2026 at 2:00PM, the GS confirmed the laboratory did not have an established policy to follow for consultant competency prior to 2026.
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 review of the laboratory's policy for Allogenic Hematopoietic Cell Transplantation, Oragene Dx manufacturer instructions for DNA Saliva Kits, laboratory test volumes, and interview with the General Supervisor (GS), the laboratory failed to establish and follow conditions for specimen transportation (temperature) of the Oragene Dx Saliva Kits sent to the laboratory for 349 of 349 specimens in 2024 and 2025. Findings Included: 1) Review of the laboratory's policy titled 'NIH Clinical Center Department of Transfusion Medicine Allogenic Hematopoeitic Cell Transplantation (HCT) Protocol Service Agreement' did not reveal requirements for specimen transportation/storage temperatures. 2) Review of the Oragene Dx manufacturer instructions titled 'Oragene Dx OGD-500, 510, 600, 610 User Instruction' stated the following: "Storage: 15 to 30 degrees Celsius". 3) Review of the laboratory's test volumes revealed 182 and 167 Oragene Dx Saliva specimens received in 2024 and 2025 without verifying specimen temperatures upon receipt and transit. 4) In an interview on 4/20/2026 at 4:40 PM, the GS confirmed the laboratory did not include specimen transportation requirements for temperature in its protocol, and did not have a system to verify specimen transportation temperatures stayed within manufacturer required ranges and upon receipt.
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: I. Based on direct observation, review of manufacturer instructions, laboratory Reese Monitoring temperature records, and interview with the General Supervisor (GS), the laboratory failed to define temperatures for freezers and room temperature consistent with manufacturer instructions for 34 of 34 CareDx AlloSeq Tx17, OneLambda LABScreen Single Antigen HLA Class I & II, and Quality Biological PBS reagents. Findings Included: 1) During a laboratory tour on 4/20/2026 at 4:28 PM, the following reagents were observed stored in the respective locations: a. 1 Quality Biological Phosphate Buffered Saline (PBS) reagent bottle, Lot Number 726555, Manufacturer Storage Temperature Requirements: Room Temperature (15 to 30 degrees Celsius) Location: 2-8 refrigerator, Rees Scientific Input Number 10, Node 2, NIH Property Number: 02268853, Serial Number: 1143172301230109 b. 9 CareDx AlloSeq Tx17 reagent boxes, Lot Number 25-6300, Manufacturer Storage Temperature Requirements -25 to -15 degrees Celsius Location: Room 2N214A -25 to -10 degrees Celsius freezer, Rees Scientific Input Number 26, NIH Property Number: 02330570 c. 6 One Lamba LABScreen Single Antigen HLA Class I Combi + Wash Buffer reagents, Lot Number 016, Batch Number 0000873699, Manufacturer

	Storage Temperature Requirements -65 Celsius or colder. Location: Room 2N214A, -75 to -55 Celsius HLA freezer, Reese Scientific Input Number 5 d. 12 One Lambda LABScreen Class 1 Bead Mix + Wash Buffer reagents, Lot Number 022, Batch Number 0000936034, Manufacturer Storage Temperature Requirements -65 Celsius or colder. Location: Room 2N214A, -75 to -55 Celsius HLA freezer, Reese Scientific Input Number 5 e. 2 One Lambda LABScreen PRA Class II Bead Mix + Wash Buffer Reagents, Lot Number 021, Batch Number 0000882808, Manufacturer Storage Temperature Requirements -65 or colder. Location: Room 2N214A, -75 to -55 Celsius HLA freezer, Reese Scientific Input Number 5 f. 4 One Lamba LABScreen Single Antigen HLA Class II - Group 1 + Wash Buffer Reagents, Lot Number 017, Batch Number 0000880214, Manufacturer Storage Temperature Requirements -65 or colder. Location: Room 2N214A, -75 to -55 Celsius HLA freezer, Reese Scientific Input Number 5. 2) Review of the laboratory's Reese Scientific room temperature settings revealed an acceptable range of 18 to 28 degrees Celsius. The laboratory's room temperature log sheet defined an acceptable temperature range as 19 to 26 degrees Celsius. 3) In an interview on 4/20/2026 at 4:30 PM, the GS confirmed the defined temperature ranges on the Reese Scientific continuous temperature monitoring system were not consistent with manufacturer requirements and temperature log sheets. II. Based on direct observation, review of manufacturer instructions, laboratory policies, lack of humidity records and interview with the General Supervisor (GS), the laboratory failed to define, monitor and document humidity in the laboratory for 2 of 2 years (2024 and 2025). Findings Included: 1) During a laboratory tour on 4/20/2026 at 4:37 PM, 2 Illumina MiSeq System analyzers were observed in use, (Serial Numbers M08636, M07700). 2) Review of the Illumina MiSeq System manufacturer specification sheet (M-GL-00006 v4.0) stated the following humidity requirements on page 5: "Operating environment: Humidity - Noncondensing 20%-80%" 3) Review of the laboratory's written policies revealed no defined humidity ranges. 4) The laboratory could not provide documentation of recording humidity on each day of patient testing for 2024 and 2025. 5) In an interview on 4/20/2026 at 4:40PM, the GS confirmed the laboratory did not define, monitor and document humidity.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (b)(3) Providing orientation to all testing personnel; and (b)(4) Evaluating and documenting the competency of all testing personnel. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Centers for Medicare and Medicaid Services (CMS) Form 209, Policies and Procedures, personnel competency records, and interview with the General Supervisor (GS), the GS failed to evaluate and document the competency of 1 of 10 Testing Personnel for two years (2024 and 2025). Findings Included: 1) Review of the laboratory's CMS Form 209 revealed 10 TPs performing high complexity testing. 2) Review of the laboratory's policy titled 'NIH Clinical Center Department of Transfusion Medicine HLA SOP-7020, Version 2.0, HLA Training and Competency Assessment Plan' stated the following on page 2 of 6: "6.0 Competency Assessment 6.1 Evaluate laboratory staff annually on the six assessment procedures required by CLIS: 6.11 Document the completion for each assessment element on HLA FRM-7330 HLA Laboratory Annual Competency Assessment for each employee... 6.1.3.2 Confirm that each employee correctly records, interprets and reports testing results... 6.1.7 The HLA Laboratory Supervisor

	will review HLA FRM-7330 HLA Laboratory Annual Competency Assessment for completeness and determine if any additional action is required..." 3) Review of the laboratory's competency records revealed missing competencies for TP#10 for 2024 and 2025. 4) In an interview on 4/20/2026 at 4:26 PM, the GS confirmed TP#10 monitored, reviewed and reported test results, but did not have a competency assessment to assess performance of these testing personnel responsibilities.