Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0709776	09/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Histocompatibility Laboratory	410 W 10th Ave, N-937 Doan Hall, Columbus, OH	

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 Surveyor from the Centers for Medicare& Medicaid Services (CMS) Survey Branch conducted a Validation survey on 9/5/2025. The following standard level deficiencies were 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 Centers for Medicare and Medicaid Services (CMS) Form 209, laboratory policies, competency assessments, and confirmed in interview with the General Supervisor (GS), the laboratory failed to have documentation of a policy to address competency assessments for one of one GS in 2024 and 2025. Findings Included: 1. Review of the CMS-209 form submitted by the laboratory at the time of survey, revealed one individual newly designated the GS role in March 2025. 2. Review of the laboratory's policies revealed no documentation of a policy to address competency assessment performance of individuals in the GS role. 3. Review of the laboratory's competency assessments revealed no competency documentation for the GS. 4. In an interview on 9/05/2025 at 1:00 PM, the GS confirmed the laboratory did not have an established policy for GS competency assessment and did not assess competency for the consultant role(s) beyond using the same six-point competency assessment also utilized for testing personnel (TP).
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 lack of laboratory procedures, and interview with the General Supervisor (GS), the laboratory failed to establish a procedure for specimen transport criteria for six of six test-types sent from external providers/laboratories. Findings Included: 1. Review of the laboratory's list of tests performed from serum and whole blood patient samples transported from external providers/laboratories revealed the following histocompatibility tests with no established procedure for specimen transport criteria: a. ACC-Ab-SAB1 b. ACC-ALLO-SAB2 c. ACC-AlloXM d. ACC-SingleCL1 e. ACC-SingleCL2 f. ACC-Solid Organ 2. Review of the laboratories test volumes for 2024 and 2025 revealed the following samples sent from external providers /laboratories: a. 2024: ACC-Ab-SAB1 - 336 tests performed ACC-ALLO-SAB1 - 304 tests performed ACC-AlloXM - 56 tests performed ACC-SingleCL1 (Single-Locus HLA Typing) - 38 tests performed ACC-SingleCL2 (Single-Locus HLA Typing) - 1 test performed ACC-Solid Organ - 61 tests performed b. 2025: ACC-Ab-SAB1 - 209 tests performed ACC-ALLO-SAB1 - 201 tests performed ACC-AlloXM - 35 tests performed ACC-SingleCL1 (Single-Locus HLA Typing) - 20 tests performed ACC-SingleCL2 (Single-Locus HLA Typing) - 1 tests performed ACC-Solid Organ - 28 tests performed 3. In an interview on 9/05/2025 at 1:15 PM, the GS confirmed the laboratory did not have specimen transportation requirements as part of their standard operation procedure (SOP) available to external providers/laboratories for the aforementioned tests. Word Key: SAB - Single Antigen Beads Assay (SAB) HLA - Human Leukocyte Antigen (HLA)
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer instructions, test volume records, and interview with the Testing Personnel (TP)-2, based on the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to follow the manufacturer's instructions for storage of one of one bottle of Applied Biosystems Hi-Di Formamide. Findings Included: 1. In direct observation on 9/05/2025 at 12:58 PM in Room N943, one bottle of Applied Biosystem Hi-Di Formamide, Lot #2407955, was seen stored in the 2 to 8 degree Celsius (C) refrigerator (Frigidaire Serial Number WB03430-363, T08434307). 2. Review of the manufacturer's instructions titled 'Applied Biosystems Hi-Di Formamide SeqStudio Flex and 3500 series instruments, Catalog Number: 4401457' stated the following storage instructions: "Storage: -25 to -15 degrees Celsius, If frequent sampling is required, dispense and freeze small aliquots of Hi-Di Formamide into smaller tubes. Minimize freeze-thaw cycles and exposure to air and room temperature because the quality of the material can decrease when exposed to

	air." 3. In an interview on 9/05/2025 at 1:00 PM, TP-2 confirmed the laboratory stored the Hi-Di Formamide reagent bottle in the 2 to 8 C refrigerator, and did not follow manufacturer's instructions for storing the reagent in a -25 to -15 C freezer.
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 direct observation, manufacturer's instructions, and interview with the Testing Personnel (TP)-2, according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to define temperature ranges of the Thermo freezer consistent with manufacturer instructions for 5 of 5 Sigma-Aldrich Human Serum bottles. Findings Included: 1. In direct observation 9/05/2025 at 12:55 PM in Room N935, 5 bottles of Sigma-Aldrich Human Serum bottles, Lot #0000399530, Manufacturer storage temperature requirements -20 degrees Celsius, were stored in the -80 degrees Celsius freezer (Thermo, Serial Number 1119439401181105, T0420078). 2. In an interview on 9/05/2025 at 1:00 PM, TP-2 confirmed that the serum bottles were kept in a freezer and had a temperature range not consistent with manufacturer instructions.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: I. Based on direct observation, manufacturer's instructions, and interview with the Testing Personnel (TP)-2, according to the Centers for Medicare and Medicaid Services (CMS) Form 209, the laboratory failed to establish performance specifications of a reagent for which expiry dates were not provided by the manufacturer, for one of one Invitrogen UltraPure 10x TBE Buffer. Findings Included: 1. In direct observation on 09/05/2025 at 12:50 PM in the Gel Electrophoresis room of the laboratory, one Invitrogen UltraPure 10x TBE Buffer, Lot

	#2507360, was observed with no expiration date provided by the manufacturer, and an open date of 2/10/2023. 2. In an interview on 9/05/2025 at 1:00 PM, Testing Personnel (TP)-2 confirmed the buffer reagent had been in use since February 2023, and did not have a manufacturer expiration date. The laboratory had not established an expiration date of its own. II. Based on direct observation, manufacturer's instructions, and interview with the Testing Personnel (TP)-2, the laboratory failed to establish performance specifications after modifying manufacturer storage instructions for one of one Cytiva Phosphate Buffered Saline. Findings Included: 1. In direct observation on 9/05/2025 at 12:46 PM in Room N935, one Cytiva Phosphate Buffered Saline bottle, Lot #AK30802617, Manufacturer storage instructions 15 to 30 degrees Celsius (C), was seen in storage in the 2 to 8 C refrigerator (Fisherbrand 300411319, T04199325). 2. In an interview on 9/05/2025 at 1:00 PM, Testing Personnel (TP)-2 confirmed the laboratory stored the reagent in the refrigerator without establishing performance specifications after modifying storage temperatures.