Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1059182	(X3) Date Survey Completed 08/27/2025
Name of Provider or Supplier Uh Histocompatibility Laboratory	**Street Address, City, State** 10524 Euclid Ave Wo Walker Center, Cleveland, 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
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 general supervisor interviews and written preanalytic policies and procedures record review on August 26, 2025 at 01:30 pm, the laboratory failed to establish written procedures for the conditions for patient specimen transportation. Findings included: a. It was the practice of the laboratory to have a courier service transport patient specimens form referring facilities to the laboratory. b. The laboratory maintained limited written policies and procedures detailing the conditions for patient specimen transportation for these referred patient specimens which included information indicating that patient specimens temperatures should be maintained at "room temperature." However, the laboratory maintained no written policies and procedures defining "room temperature." c. According to laboratory records, the laboratory performed and reported 18,034 patient tests annually.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

	This STANDARD is not met as evidenced by: Based on general supervisor interviews and disease-associated antigen testing record review on August 27, 2025 at 12:00 pm, for the laboratory's disease-associated antigen testing qualitative procedure, the laboratory failed to included negative and positive quality control materials at least once each day patient specimens are assayed. Findings included: a. It was the practice of the laboratory to perform and report patient disease-associated antigen testing, such as HLA B27 testing, using LABType SSO (Sequence-Specific Oligonucleotide) DNA typing methodology. b. On July 29, 2025, for specimen 25HL-207HLA0002, the laboratory reported a test result of "HLAB27 Typing Negative." The laboratory maintained no documentation to indicated that on the day this specimen was assayed (July 29, 2025) the laboratory had assayed negative and positive HLAB27 antigen quality control materials. c. The general supervisor confirmed these findings on August 27, 2025 at 12:00 pm. d. According to the general supervisor, the laboratory performed and reported approximately 50 patient disease-associated antigen tests annually.
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 general supervisor interviews and written competency policies record review on August 26, 2025 at 11:00 am, the laboratory director, high complexity testing, failed to ensure that procedures were 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. Findings included: a. Although the laboratory maintained documentation to indicate that it had met the requirement at 42 CFR 493.1451(b)(8), the laboratory maintained no written procedures detailing the laboratory's process for determining an individuals' documented competency. b. These findings were confirmed by a general supervisor on August 26, 2025 at 11:00 am. c. According to laboratory records, the laboratory performed and reported 18,034 patient tests annually.