

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0664468	(X3) Date Survey Completed 09/24/2026
Name of Provider or Supplier Histocompatibility & Immunogenetics	Street Address, City, State 1700 Perdido Street, Room 308, New Orleans, LA	
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 September 24, 2026. The laboratory was found to be in compliance with condition level deficiencies. The following standard-level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's written policies and procedures, turnaround times (TATs), and interview with the Laboratory Director (LD), the laboratory failed to follow its own policy for meeting turnaround times for 1 of 3 months (Random review April to June 2026) Findings Included: 1) Review of the laboratory's written policy titled 'TUHLA Laboratory Policies' stated the following on page 12 of 18: "E. Turnaround Time i. TUHLA will report results timely. Due to the complexity of histocompatibility testing, TAT is longer than most diagnostic testing and may vary depending on the condition of the sample and a need to repeat failed testing or conduct reflex testing. The TATs for specific tests are in the test menu attached to relevant testing agreements ..." 2) Review of the laboratory's monthly TATs revealed a monthly TAT acceptable threshold of 85% and the following TATs not met between April and June (Random Review): a. June 2026, 601 histocompatibility samples tested, 83% TATs met (499/601) 3) In an interview on 9/24/26 at 12:15 PM, the LD confirmed the findings of some of the laboratory's TATs not meeting policy and test-menu defined thresholds.
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's instructions and interview with the Laboratory Director (LD), the laboratory failed to define, monitor and document temperatures in the Chemical room and Storage room for 5 of 5 Thermo Fisher Scientific Dulbecco's Phosphate Buffer Saline (PBS) reagents and 3 of 3 boxes of Becton Dickinson (BD) Vacutainer tubes. Findings Included: 1) During a laboratory tour on 9/24/26 at 12:00 PM, the Laboratory Chemical Room and Storage rooms had the following temperature dependent reagents and supplies stored with no temperatures defined, monitored and documented: a. Chemical Room - 5 Thermo Fischer Scientific Dulbecco's PBS reagents, Lot Number 3335596, Manufacturer storage temperature requirements 15 to 30 degrees Celsius. b. Storage Room - 3 boxes of BD Vacutainer Serum Separator Tubes (SST), Lot Number 6071117, Manufacturer storage temperature requirements 4 to 25 degrees Celsius. 2) In an interview with the LD on 9/24/26 at 12:15 PM, the LD confirmed the chemical and storage rooms did not have temperatures defined, monitored and documented. II. Based on direct observation, review of manufacturer's instruction and interview with the Laboratory Director (LD), the laboratory failed to define, monitor and document humidity in the Monoclonal Antibody Laboratory section where 4 of 4 Luminex instruments were in use. Findings Included: 1) During a laboratory tour on 9/24/26 at 12:00 PM, the following instruments were observed in use in Room 315 Monoclonal Antibody Lab with no humidity monitored, documented or recorded: a. 2 Luminex 200 instruments (Serial Numbers 10008340402 and 10006257407) b. 2 Luminex Flex Map 3D instruments (Serial Numbers FM3DD14227001, FM3DD24162022) 2) Review of the manufacturer's instructions for the Luminex instruments revealed the following: a. 'Luminex 200 System User Manual, PN 89-00002-00-109 Rev. A', page 2: - "Humidity 20 to 80% noncondensing" b. 'Luminex FLEXMAP 3D Hardware User Manual IVD' - "Shipping and storage humidity: 20 to 80% noncondensing" 3) In an interview on 9/24/26 at 12:15 PM, the LD confirmed Room 315 did not have defined humidity ranges and hygrometer to monitor and document humidity.