Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0994686	06/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Tulane University Health Sciences Center	1430 Tulane Avenue, 86-79, Room 6524, 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 Recertification survey was performed at Tulane University Health Sciences Center, CLIA ID 19D0994686, on June 10, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with personnel, the laboratory failed to ensure the proficiency testing attestation statements for Immunohistochemistry were signed by testing personnel and/or the Laboratory Director for two (2) of three (3) events reviewed. Findings: 1. Review of the laboratory's proficiency testing records revealed the laboratory enrolled in the College of American Pathologists (CAP) proficiency testing (PT) program to verify the accuracy of Immunohistochemistry testing. 2. Review of the 2024 and 2025 CAP Immunohistochemistry PT records revealed the following documentation was not completed: 2024: MK-A event for Immunohistochemistry, the Laboratory Director did not sign the attestation statement 2025: MK-A event for Immnnohistochemistry,

	the Laboratory Director and Testing Personnel did not sign the attestation statement 3. In interview on June 10, 2025 at 12:56 pm, the General Supervisor confirmed the identified PT events did not have signed attestation statement forms.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the laboratory failed to label reagents in secondary containers with the correct expiration date. Findings: 1. Observation by surveyor during the laboratory tour on June 10, 2025 at 9:38 am revealed the following reagents in secondary bottles: a) 3% Acetic Acid " Prep date 5 /15/23 Exp date 8/15/23" with the following note on bottle "Never use expired reagent." b) 95% Ethanol: "Prep date 6-9-25 Exp 5-31-20, lot 227850" 2. In interview on June 10, 2025 at 10:20 am, the General Supervisor stated the 3% Acetic Acid is made by personnel weekly. The General Supervisor stated the bottle is not updated with the current preparation and expiration dates. 3. In interview on June 10, 2025 at 10:20 am, Personnel 1 stated she prepared the identified 95% Ethanol on June 9, 2025 as listed and not put the correct expiration date on the secondary bottle.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5415.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with personnel, the laboratory failed to maintain the attestation statements for two (2) of three (3) testing events reviewed. Refer to D2014.