Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2315689	11/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Waterside Dermatology Pllc	300 Riverside Dr E Suite 2200, Bradenton, FL	

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 announced CLIA initial certification survey was conducted at Waterside Dermatology PLLC on 11/18/2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observations and interview, the laboratory used two expired tissue marking dyes for one (10/2025) of three months (10/2025, 06/2025, 04/2025) selected for review. Findings included: 1. During a tour of the laboratory on 11/18/2025 at 11:00 a. m., a bottle of opened black & yellow tissue marking dye were observed with an open date of 03/04/2025 and an expiration date of 09/30/2025. 2. The accession log was reviewed. Patient testing was performed in 10/2025. 3. Interview with the Laboratory Director on 11/18/2025 at 1:25 p.m. confirmed the above. Photographic evidence taken.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) provide a safe environment in which employees are protected from physical, chemical, and biological hazards; This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the Laboratory Director failed to

	ensure employees were protected from chemical hazards from 03/11/2025 to the date of survey 11/18/2025. Findings included: 1. Observations of the laboratory were conducted during a tour on 11/18/2025 at 11:00 a.m. No fume hood was present. 2. Safety Data Sheet(s) (SDS) for reagents were reviewed. A. The SDS for Eosin Y, Alcoholic 0.25%, with a revision date of 09/09/2014 showed "Do not breathe mist, spray, vapors." B. The SDS for 100% Reagent Alcohol, with a revision date of 12/27 /2018 showed not to breath the reagent fumes, gas, mist, or vapor. C. The SDS for UltraClear Xylene Substitute, with a revision date of 10/05/2016 showed to avoid breathing vapors, mist, or spray. 3. The Laboratory Director was interviewed on 11/18 /2025 at 1:25 p.m. They confirmed there was no fume hood present to prevent the inhalation of the above reagent vapors. Photographic evidence taken.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to implement the quality assessment program (quality assurance) from 03/2025 through 10/2025. Findings included: 1. The laboratory policy and procedure manual, signed by the Laboratory Director 03/11/2025 was reviewed. The policy titled Quality Assurance required the Laboratory to review and sign a Monthly Quality Assurance Checklist. 2. No completed Monthly Quality Assurance Checklists could be located for 03/2025 through 10/2025. 2. An interview conducted with the Laboratory Director on 11/18 /2025 at 1:25 p.m., confirmed they had not documented any monthly quality assurance since opening 03/2025.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to document one of one Testing Personnel (TP #B), who was required to have competency evaluations, had demonstrated they could accurately perform grossing (macroscopic) and slide interpretation (microscopic) for the subspecialty of Histopathology prior to performing patient testing. Findings included: 1. Form CMS-209, Laboratory Personnel Report, signed by the Laboratory Director on 11/18/2025 was reviewed. 2. No documentation of an initial competency evaluation for Testing Personnel #B was available. 3. Interview with the Laboratory Director on 11/18/2025 at 1:25 p.m. confirmed there was no evaluation that showed Testing Personnel #B could accurately perform grossing and slide interpretation prior to performing the aforementioned patient testing.