Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2273360	08/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Waterway Dermatology Pllc Dba	20 Waterway Rd, Tequesta, 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 recertification survey was conducted at Waterway Dermatology PLLC on 8/14/2025 to 8/18/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400 493.1250 Condition: Analytic Systems D6076 493.1443 Condition: Laboratory Director High Complexity
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to ensure protection from chemical hazards. Findings include: 1. During the laboratory tour on 08/14/25 at 10:37 AM, Plantinumline Xylene Substitute, Avantik 95% Alcohol, Mercedes 100% Reagent Alcohol, Avantik Ultra Clear Xylene Substitute, and Mercedes Hematoxylin were observed stored in the flammable safety cabinet for use with Patient Histology testing. All of the listed reagents had hazard labels for respiratory health hazard and directed to not breathe mist/vapors/spray. 2. The laboratory failed to have a fume hood or air quality monitoring device to ensure protection from chemical hazardous fumes from the reagents listed used by the laboratory. 3. During the laboratory tour on 08/14/25 at 10:37 AM the eye wash bottle was observed to have expired on 07/25. 4. The Practice Manager at on 08/14/25 at 10: 37 AM, confirmed the laboratory was not aware protection from chemical hazardous fumes was required and that the available eyewash bottle was expired. 5. The Laboratory Director stated via phone call on 08/14/25 at 12:40 PM, that he was not aware respiratory protection was required for the reagents used in the performance of Histology testing.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify accuracy twice annually from 10/2023 to 8/14/2025 for Testing Person (TP) A and B and TP C from 1 /2025 to 8/14/2025 for testing performed in the subspecialty of Histopathology. Findings included: 1. The laboratory's Policies and Procedure Manual reviewed and signed by the Laboratory Director on 01/30/23 in the Quality Assurance (QA) Manual portion under VII noted, any tests performed in laboratory for which proficiency testing is not available will be verified at least twice a year and the Laboratory Director will review the results. 2. The CMS-209 signed by the Laboratory Director 08 /14/25 listed three Testing Personnel. TP A and TP B had been listed on the CMS-209 dated 9/27/23 from the initial certification survey. The Laboratory Director stated during phone interview on 8/14/25 at 12:40 PM, that TP C began patient testing at the laboratory 01/01/2025. 3. Personnel and QA-Proficiency records were reviewed for 10 /2023 to 08/2025, however the only QA-Proficiency records found were for TP A and TP B dated 9/2023 which was prior to the initial survey. The Practice Manager on 08 /14/25 at 12:40 PM, was not able to locate any further twice yearly QA-Proficiency records for TPs A, B, or C. 4. The Laboratory Director on 08/14/25 at 12:40 PM, via phone stated the twice yearly QA-Proficiency records for TPs A, B, or C should be in the records but they were not able to explain where the records were filed.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to monitor and document the temperature and humidity of the room and cryostat used for patient Histology testing from 12/11/2023 to 10/28/24 (See D5413); three of three tissue inks used for Histology patient testing were not labeled with identity, preparation, and expiration dates (See D5415); the lab utilized an expired reagent, for Histology for a year (2024 to 2025) (See D5417); and the laboratory failed to monitor and document the maintenance of the cryostat used for patient Histology testing from 12/11/2023 to 10 /28/24 and stainer from 12/11/23 to 4/1/24 and 5/6/24 to 10/28/24 (See D5433).
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 record review and interview, the laboratory failed to monitor and to document the temperature and humidity of the room and cryostat used for Patient Histology testing from 12/11/2023 to 10/28/24. Finding include: 1. The laboratory Mohs Laboratory Quality Control log filed in the 2024 binder listed areas to document the daily laboratory temperature, laboratory humidity, and cryostat temperature. There was no documentation of daily laboratory temperature, laboratory humidity, or cryostat temperature from 12/11/2023 to 10/28/24. 2. The 2024 Mohs Accession Log documented patient Histology testing was performed on 01/29/24, 03/04/24, 04/01/24, 05/06/24, 06/17/24, 07/29/24, and 09/16/24. There was no daily monitoring of the laboratory temperature, laboratory humidity, and cryostat temperature from 12/11 /2023 to 10/28/24. 3. The Practice Manager confirmed on 08/14/25 at 11:30 AM, the lack of daily monitoring of the laboratory temperature, laboratory humidity, or cryostat temperature from 12/11/2023 to 10/28/24. 4. The Laboratory Director stated on 08/14/25 at 12:40 PM, via phone he was not aware of the missing monitoring of the daily laboratory temperature, laboratory humidity, or cryostat temperature from 12 /11/23 to 10/28/24.
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, interview, and record review, three of three tissue inks used for Histology patient testing failed to be labeled with identity, preparation, and expiration dates. Findings Include: 1. On 08/14/25 at 10:40 AM, three of three Formalin containers filled with tissue inks used for Histology patient testing failed to be labeled with identity, preparation and expiration dates. 2. The Practice Manager confirmed on 08/14/25 at 10:40 AM, three of three Formalin containers filled with tissue inks used for Histology patient testing did not have labels with identity, preparation date or expiration dates 3. The Laboratory Reagent Logs for 2024 and 2025 failed to have documentation of lot number, expiration date, and date received for Tissue Ink.
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 observation, record review, and interview, the laboratory failed to use reagents for Histology that were not expired for one year (2024 to 2025). Findings included: 1. During tour of the laboratory on 8/14/25 at 10:40 AM, the Tissue Ink used for Histology testing was observed to have expiration dates of 4/30/24, 7/31/24, and 6/30/24. There was no other Tissue Ink available for use in the laboratory. 2. The laboratory reagent logs for 2024 and 2025 did not include monitoring of the Tissue Ink used for patient testing. 3. The Practice Manager verified on 8/14/25 at 10:40 AM, the Tissue Ink in use had expired in 2024.. 4. The Laboratory Director stated on 8/14 /25 at 12:40 PM, expiration dates were monitored on the laboratory reagent logs, but was not aware the Tissue Ink was not included in the monitoring. He was not aware expired reagent had been used for patient testing.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to monitor and document maintenance of the cryostat used for patient Histology testing from 12/11/2023 to 10 /28/24 and stainer from 12/11/23 to 04/01/24 and 05/06/24 to 10/28/24. Finding include: 1. The laboratory Mohs Laboratory Quality Control log filed in the 2024 binder listed an area to document the daily laboratory maintenance of the cryostat and the H & E (Hematoxylin & Eosin) Stainer Log maintenance used for patient Histology testing. There was no documentation of maintenance of the cryostat used for patient Histology testing from 12/11/2023 to 10/28/24 and stainer from 12/11/23 to 04/01/24 and 05/06/24 to 10/28/24. 2. The 2024 Mohs Accession Log documented patient Histology testing was performed on 01/29/24, 03/04/24, 04/01/24, 05/06/24, 06 /17/24, 07/29/24, and 09/16/24. There was no documented maintenance for the cryostat and stainer on these dates. 3. The Practice Manager confirmed on 08/14/25 at 11:30 AM, the lack of listed daily monitoring of the the maintenance of the cryostat and stainer used for patient Histology testing. 4. The Laboratory Director stated on 08 /14/25 at 12:40 PM, via phone he was not aware of the missing monitoring of the the maintenance of the cryostat used for patient Histology testing and stainer.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory from 10

	/02/2023 to 08/14/2025 (See D6076); failed to establish a policy or to reflect the requirement of being onsite once every 6 months to include evidence of performing activities that are part of the Laboratory Director's responsibilities or to document a 6 month onsite visit from 1/2025 to 8/2025 (See D6080); failed to ensure the quality assessment (QA) program was maintained to assure quality of laboratory services provided and to identify failures in quality as they occur from 10/2023 to 08/2025 (See D6093); failed to ensure that prior to testing Patients' specimens, one of one new Testing Personnel (TP C) who performed Histology testing, had received the appropriate training and demonstrated they could perform all testing operations reliably to provide and report accurate results (See D6102); and failed to ensure policies and procedures were established for monitoring individuals who conducted preanalytic, analytical, and postanalytic phases of testing and to perform biannual and annual competency on one of two Testing Persons (B & C) performing testing for the subspecialty of Histopathology, (TP B) (See D6103).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, it was determined the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory from 10/2/23 to 08/14/25. Findings include: 1. The Laboratory Director failed to ensure protection from chemical hazards (See D3011), failed to ensure verification of the accuracy twice annually from 10/23 to 08/14/25 for Testing Person (TP) A and B and TP C from 01/25 to 08/14/25 for testing performed in the subspecialty of Histopathology. (See D5217) 2. The Laboratory Director failed to ensure monitoring and documentation of temperature and humidity of the room and cryostat used for patient Histology testing from 12/11/23 to 10/28/24. (See D5413) 3. The Laboratory Director failed to ensure three of three tissue inks used for Histology patient testing were labeled with identity, preparation and expiration dates. (See D5415) 4. The Laboratory Director failed to ensure the lab did not utilize expired reagent, for Histology for a year, (2024 to 2025). (See D5417). 5. The Laboratory Director failed to ensure monitoring and documentation of the maintenance for the cryostat used for patient Histology testing from 12/11/2023 to 10/28/24 and stainer from 12/11/23 to 04/01/24 and 05/06/24 to 10/28/24. (See D 5433) 6. The Laboratory Director failed to establish a policy or to reflect the requirement of being onsite once every 6 months to include evidence of performing activities that are part of the Laboratory Director's responsibilities or to document a 6 months onsite visit from 01 /25 to 08/25. (See D6080) 7. The Laboratory Director failed to ensure the Quality Assessment (QA) program was maintained to assure quality of laboratory services provided and to identify failures in quality as they occurred from 10/23 to 08/25. (See

	D6093) 8. The Laboratory Director failed to ensure that prior to testing patients' specimens, one of one new Testing Personnel (TP C) who performed Histology testing, had received the appropriate training and demonstrated competency to perform all testing operations reliably and report accurate results. (See D6102) 9. The Laboratory Director failed to ensure policies and procedures were established for monitoring individuals who conduct preanalytic, analytical, and postanalytic phases of testing and to perform biannual and annual competency on one Testing Person (TP) B of two Testing Persons (B & C) performing testing for the subspecialty of Histopathology. (See D6103).
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to establish a policy or to reflect the requirement of being onsite once every 6 months to include evidence of performing activities that are part of the Laboratory Director's responsibilities or to document a 6 month onsite visit from 1/2025 to 8/2025. Findings included: 1. The Policy and Procedure Manual, which had approval date of 1/30/2023 was reviewed. No policy could be found regarding documenting being on site every 6 months to include evidence of performing activities that are part of the Laboratory Director's responsibilities. 2. The Laboratory Director stated on 8/14/25 at 12:40 PM, via phone that he was not aware of this requirement and had added a procedure or to perform and document an onsite visit.
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, it was determined the Laboratory Director failed to ensure the quality assessment (QA) program was maintained to assure quality of laboratory services provided and to identify failures in quality as they occur from 10 /2023 to 08/2025. Findings include: 1. The laboratory's Policies and Procedures Mohs Quality Assurance Manual was approved by the Laboratory Director 1/30/2023. XII. Quality Assessment Review with Staff noted the Laboratory Director would discuss with staff quarterly the results of quality assurance reviews and ways to improve the laboratory quality. 2. QA records from 12/24 to 08/14/25 were provided for review at the time of the survey that included a Monthly Quality Assurance Checklist dated 12 /2024 with all marked as yes to indicate all line items were met. There was a line for signature and date of review which was empty. Monthly Patient Quality Assurance

	Checklists, which were filed in the 2025 binder, dated 01/13, 02/24, 03/31, 04/14, and undated form all marked as yes to indicate all line items were met. There was a line for signature for the Laboratory Director which was empty. There was no documentation of quarterly review with staff or any identification of improvements needed. There was no documentation of QA for 05/25 to 08/25. 3. The Laboratory Director on 08/14/25 at 12:40 PM, via phone did not have an explanation for the missing QA documents or why there was a completed Monthly Patient Quality Assurance Checklist without a date or signature.
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 ensure that prior to testing Patients' specimens, one of one new Testing Personnel (TP C) who performed Histology testing, had received the appropriate training and demonstrated they could perform all testing operations reliably to provide and report accurate results. Findings included: 1. The laboratory's Policies and Procedure Manual was approved by the Laboratory Director on 01/30/23 that included job duties of the Laboratory Director. Item #11 read, would ensure prior to testing patients; specimens all personnel have the appropriate education and experience, receive the appropriate training and have demonstrated they they can perform all testing operations reliably to provide and report accurate results. 2. The CMS-209 Laboratory Personnel Report signed by the Laboratory Director on 8/14/25 listed one new TP C who performed Patient Histology testing since the certification survey on 10/2/23. 3. Review of TP-C's records failed to include documented training records for this laboratory prior to performing Patient testing. The Practice Manager on 08/14/25 at 12:15 PM, confirmed TP-C's records failed to include documentation of training or demonstrated competency prior to patient testing and reporting. 4. The Laboratory Director on 08/14 /25 at 12:40 PM, via phone was not able to explain lack of documentation of training or demonstrated competency prior to Patient testing and reporting for TP C.
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 record review and interview, the Laboratory Director failed to ensure policies and procedures were established for monitoring individuals who conducted preanalytic, analytical, and postanalytic phases of testing and to perform biannual and

	annual competency on one of two Testing Persons (B & C) performing testing for the subspecialty of Histopathology, (TP B). Findings included: 1. The laboratory's Policies and Procedure Manual was approved by the Laboratory Director on 1/30 /2023 and included job duties of the Laboratory Director. Item #12 read, would ensure policies and procedures were established for monitoring individuals who conduct preanalytic, analytical, and postanalytic phases of testing. Specific procedure was not found for monitoring testing personnel. Blank forms for Performance Standard Evaluation Physicians and PA performing Mycology and for Testing Personnel (Physician) CLIA Competency Assessment were reviewed but none were completed during the survey. 2. Review of the CMS-209, Laboratory Personnel Report (CLIA), signed and dated by the Laboratory Director 8/14/25 revealed TP B and TP C performed high complexity testing. TP B had been performing testing since at least 9 /27/23 and TP C since 1/1/25. 3. Review of TP B's personnel record failed to include documented competency assessments from 2023 to 2025 for Histology testing performed. 4. The Laboratory Director on 8/14//2025 at 12:40 PM, via phone call was not able to explain the missing biannual and annual competency of TP B or specific policies and procedures establishing for monitoring individuals who conduct preanalytic, analytical, and postanalytic phases of testing.