Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0694169	(X3) Date Survey Completed 12/17/2025
Name of Provider or Supplier Utsw Skin Surgery And Oncology Clinic	**Street Address, City, State** 5939 Harry Hines Blvd, Suite 400, Dallas, TX	
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 onsite recertification survey was conducted on 12/17/2025. The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, Centers for Medicare & Medicaid Services (CMS) 209 form, personnel records, and confirmed in interview, the laboratory failed to establish written procedures to ensure competency assessment for one of two Clinical Consultants (CC-2) in 2024 and 2025 who provided oversight of dermatopathology slide interpretations. Findings included: 1. Review of the laboratory's written procedures did not include a procedure for competency assessments for individuals designated as the clinical consultant, as required. The clinical consultant provided oversight of dermatopathology slide interpretations. 2. Review of the CMS 209 form and personnel records for CC-2 did not include competency assessments performed and documented based on position responsibilities as defined in Subpart M (493.1351) in 2024 or 2025. 3. During an interview on 12/17/2025 at 10:02 a.m., the Senior Histotechnician confirmed written procedures did not include performing and documenting competency assessments for the clinical consultant.
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 direct observation and confirmed in interview, the laboratory failed to ensure six of six reagents stored in secondary containers were labeled with identification, concentration, poured dates, and expiration dates. Findings included: 1. During a tour of the laboratory on 12/17/2025 at 11:35 a.m., the surveyor observed the following reagents: On the counter one Nalgene wash bottle (secondary container) labeled "TBS". The laboratory failed to label the secondary container with identification (lot numbers), concentration, poured dates, and expiration dates. Without proper labeling, the reagent could not be linked to an original container and therefore the expiration dates could not be determined. In the inking area five plastic bottles labeled "Exp 12/19". The laboratory failed to label the secondary containers with identification (name and lot numbers), concentration, and poured dates. Without proper labeling, the reagents could not be linked to original containers. 2. During an interview on 12/17/2025 at 11:41 a.m., the Senior Histotechnician confirmed the laboratory failed to ensure six of six reagents stored in secondary containers were labeled with identification, concentration, poured dates, and expiration dates.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of laboratory policy, Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and interview with staff, the Technical Supervisor (TS) failed to perform the annual competency evaluations for one of two testing persons (TP-2) performing high complexity testing in the subspecialty of dermatopathology in 2024 and 2025. Findings included: 1. Review of laboratory policy titled "Patient Test Management System (PTM) & Employee Competency stated: "Policy: The Director is responsible for evaluating the competency of testing personnel and all staff members. Each component of the Patient Test Management System (PTM) will be reviewed by the Laboratory Director or an appropriate, designated staff member every year to ensure the maintenance of the accuracy, appropriateness, and confidentiality of patient testing." 2. Review of the CMS 209 form identified TP-2 as a testing person performing high complexity testing (dermatopathology slide interpretations). 3. Review of personnel records revealed in 2024 and 2025 the technical supervisor failed to perform annual competency evaluations for TP-2. 4. During an interview on 12/17/2025 at 10:02 a.m., the Senior Histotechnician confirmed the Technical Supervisor (TS) failed to perform the annual competency evaluations for one of two testing persons (TP-2) performing high complexity testing in the subspecialty of dermatopathology in 2024 and 2025.