Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2112191	07/20/2026
Name of Provider or Supplier	**Street Address, City, State**	
Precision Skin Institute Llc	3501 S University Dr Ste 5, Davie, 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 PRECISION SKIN INSTITUTE LLC on July 20, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiency cited as follows:
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory failed to update the" MYCOLOGY/KOH" procedure with the 10% Potassium Hydroxide (KOH) in use at least from January 2025 to present. Findings included: 1-During the

	tour of the laboratory on 07/20/2026 at 10:00 AM, the surveyor observed that the laboratory had one bottle Statlab 10% KOH lot 263969 with opened date 04/20/2026 and one EMED Chlorazol Black E lot 002331 with opened date 06/19/2026. 2-Review of the procedure manual signed by the laboratory director on 06/15/2026, in the policy "'Mycology/KOH" procedure revealed that stated: "Add 1-2 drops of 20% KOH with DMSO. 3-Review of "QC WORKSHEET & DOCUMENTATION LOG KOH (DMSO) 20%/CHLORAZOL BLACK E" for 2025 and 2026 revealed that column "SOLUTION USED" it has printed "20% KOH/ BLACK E", in the logs for 2025 and 2026 in the column "SOLUTION USED" the staff added with handwriting "10% KOH". The laboratory tested 20 patients from January 2025 to present. During an interview on 07/20/2026 at 11:30 AM, the risk management representative confirmed that the laboratory failed to update the "MYCOLOGY/KOH" procedure before changing the working solution used for Mycology from 20% KOH to 10% KOH.