

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0622901	(X3) Date Survey Completed 10/09/2024
Name of Provider or Supplier Campbell Dermatology And Aesthetics	Street Address, City, State 706 Ne Evans St, McMinnville, OR	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the standard operating procedure (SOP) for Mohs surgery and interview with the Mohs Technician and the Laboratory Director (LD), the laboratory failed to include all steps required for performing this procedure. Findings include: 1. Upon review of the procedure manual produced for review during surgery, the laboratory failed to have a current, complete and LD approved procedure for Mohs surgical specimens. 2. The current procedure lacked the staining sequence and timing for each reagent in the staining sequence (either manually or by autostainer) for each step of the Hematoxylin and Eosin stain procedure, used to stain human tissue during</p>

a Mohs surgical procedure. 3. The current SOP lacked detail for stain Quality Control (QC) and how it is performed and documented each day Mohs surgery is performed. 4. The current procedure contained different temperature ranges for the Cryo-stat instrument than the procedure for equipment QC for the Cryo-stat. The Mohs procedure stated the temperature for the Cryo-stat was to be between -21 degrees Celcius to -26 degrees Celcius. The Equipment QC for the Cryo-stat stated the temperature range at -10 degrees Celcius to -30 degrees Celcius. 5. Interview with the LD and Mohs technician at 12:10 pm confirmed that the current SOP was lacking the staining sequence, QC of stain and that there was a discrepancy in the temperature range between the two (2) procedures. 6. The laboratory reports performing two hundred (200) Mohs surgical procedures annually.