

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 38D0624574	<b>(X3) Date Survey Completed</b> 12/12/2022
<b>Name of Provider or Supplier</b> Clackamas Dermatology	<b>Street Address, City, State</b> 12605 Se 97th Ave, Clackamas, OR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5407</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's written procedure manual and interview with Mohs technician (MT1), the laboratory failed to ensure that a current and approved procedure for staining Mohs surgical tissue specimens was available to staff members that perform the technical part of Mohs surgery. Findings include; 1. During review of the written Mohs surgery procedure, this surveyor asked MT1 if the process for staining of slides was current and up to date. MT1 responded "sort of". Further interview with MT1 at approximately 2:00 pm revealed that the current Mohs staining procedure was different than the one reviewed in the procedure manual. 2. A current procedure for staining of Mohs surgical specimens was demonstrated by MT1 inside a cabinet door in the staining area. The one page document did not have the Laboratory Director's (LD) signature or approval date. 3. The procedure in the laboratory's written procedure manual did not demonstrate documentation by the LD of the change in the staining procedure or the date the change occurred. 4. The laboratory reports 845 Mohs surgical procedures performed each year.</p>
<b>D6106</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the written procedure manual produced during survey and interview with Mohs technician (MT1), it was revealed that the Laboratory Director (LD) failed to ensure a current and approved Mohs procedure was available and in place for personnel performing staining of Mohs surgical specimens. Findings include: 1. During interview with MT1 at approximately 2:00 pm, it was revealed that the current staining sequence for Mohs surgical tissue specimens in the procedure manual was different from what was currently being performed in this laboratory. 2. MT1 directed this surveyor to a one page staining sequence/procedure taped inside a cabinet in the staining area. This staining procedure was different from the one in the procedure manual and lacked the LD approval signature and date.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on review of written laboratory procedures and interview with Mohs Technician (MT1) at approximately 2:30 pm, the Laboratory Director (LD) failed to specify in writing the duties and responsibilities all staff involved in the testing process for Mohs surgical specimens. Findings include: 1. During survey 12/12/2022, no written and current document detailing the duties and responsibilities of each person involved in the Mohs surgical process could be produced.