

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2096921	<b>(X3) Date Survey Completed</b>  04/19/2022
<b>Name of Provider or Supplier</b>  Chadds Ford Dermatology Pc	<b>Street Address, City, State</b>  6 Dickinson Drive 300 Bldg Suite 311, Chadds Ford, PA	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with Office Manager (OM), the laboratory failed to provide a procedure for Competency Assessment for 1 of 2 Testing Personnel (TP) who performed Grossing and Inking from 7/10/2021 to 04/19/2022. Findings include: 1. On the day of the survey, 04/19/2022 at 11:15am, review of the laboratory's procedures revealed, the laboratory did not establish a competency assessment procedure to assess 1 of 2 TP (CMS 209 personnel #2). 2. The Office Manager confirmed the above finding on 04/19/2022 at 11:40 am.</p>
<b>D5407</b>	<p>PROCEDURE MANUAL 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 laboratory's procedures and interview with the Office Manager (OM), the laboratory director (LD) did not approve, sign and date 8 of 8 laboratory procedures before use from 07/10/2021 to 04/19/2022. Findings include: 1. On the day of the survey, 04/19/2022 at 10:39 am, the laboratory failed to provide</p>

documentation that the LD signed and approved the following Laboratory procedures:  
-Mohs Surgery -Procedure for Submission of Biopsies -Procedure for Handling Fresh Tissue from Mohs Surgery -Procedure for Cutting Tissue on the Cryostat -Procedure for Staining Tissue - Quality Control -Safety Procedures -Daily Lab Maintenance 2. The Office Manager (OM) confirmed the findings of no signatures on 04/19/2022 at 11:40am.

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(12)

The laboratory director must 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 lack of documentation and interview with Office Manager (OM), the laboratory failed to provide documentation for 1 of 2 testing personnel (TP) that demonstrates they can perform all testing operations to provide and report accurate results from 02/22/2022 to 4/19/2022. Findings include: 1. On the day of the survey, 04/19/2022 at 11:36am, the laboratory was unable to provide documentation for 1 of 2 TP (CMA 209 personnel #2) for the in house training for Grossing and Inking. 2. The OM confirmed the findings above on 04/19/2022 at 11:40am.