

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2019621	(X3) Date Survey Completed 10/16/2018
Name of Provider or Supplier Warren Skin Care Center, Pa	Street Address, City, State 2209 Lehigh Street, Easton, PA	
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
D5407	<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 observation, review of 1 of 1 procedure manual and interview with the histopathology technician, the laboratory failed to have the procedure manual in use, signed by the current director. Findings include: 1. On the day of survey, 10/16/2018, review 1 of 1 histopathology procedure manual revealed that the procedure was not signed by the current laboratory director. 2. The histopathology technician confirmed the finding above on 10/16/2018 around 8:45 am.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on tour of the laboratory, observation of reagents, solutions and interview with the histopathology technician, the laboratory failed to label open and expiration dates, proper to use of reagents and solutions from 2017 to the day of survey. Findings Include: 1. On the day of survey, 10/16/2018, while on tour of the laboratory, it was discovered that the laboratory did not write the open and expiration dates on all</p>

reagents and solutions in use from 05/02/2017 to 10/16/2018. 2. While on tour, it was discovered that the following items were not labeled with expirations dates: - 2 of 2 bottles of Blue Davidson Tissue Marking Dyes. - 1 of 1 bottle of EKI (Chemical Company) Ammonium Hydroxide 28-30%, 500 ml bottle, Lot#1428823. 3. The histopathology technician confirmed the findings above on 10/16/2018 around 09:15 am.