Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1038213	01/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Warren Skin Care Center	755 Memorial Parkway, Phillipsburg, NJ	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: a. Based on surveyor review of the Procedure Manual (PM), Leica Operators Manual (LO) and interview with the Testing Personnel (TP), the laboratory failed to have the correct temperature range for the Leica Cryostat in the PM from 2/3/17 to the date of survey. The TP confirmed on 1/17/19 at 1:45 pm the laboratory did not follow the LO. b. Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow their Microscope Use Protocol (MP) procedure from 2/3/17 to the date of the survey. The finding includes: 1. The MP stated: "Microscope stage and ocular pieces are to cleaned every day" but there was no documented record microscope was cleaned daily. 2. The TP confirmed on 1 /17/19 at 2:00 pm that the PM was not followed.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Temperature Log (TL) and interview with Testing Personnel (TP), the laboratory failed to monitor and document Room Temperature (RT) and Humidity where Histopathology tests were performed from 2/13/17 to the date of survey. The TP confirmed on 1/17/19 at 1:20 pm that the laboratory did not document RT and Humidity.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on surveyor review of the Mohs Log (ML) and interview with the Testing Personnel (TP), the laboratory failed to maintain an accurate ML for Mohs test from 2 /13/17 to the date of survey. The findings include: 1. Review of ML revealed: a. The repair column did not have a repair listed. b. The "# of slide" column did not have a slide count. c. The Stage column was not completed. d. The "Cryostat Temp" did not have temperature recorded, but had the number of slides recorded. 2. The TP confirmed on 1/17/19 at 2:30 pm that the laboratory did not maintain an accurate ML.