

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2019621	(X3) Date Survey Completed 03/18/2025
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
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the Testing Personnel (TP), the laboratory director (LD) failed to ensure Quality Assessment (QA) programs were maintained to assure the quality of laboratory services and to identify failures in quality as they occur for 21 out of 21 months from May 2023 to February 2025. Findings include: 1. The laboratory's Quality Assurance policy states: " The Laboratory Director or an appropriate, designated staff member will conduct meetings with all relevant staff every month to communicate the results of corrective action, QC and QA reviews and to address any concerns affecting laboratory performance." 2. On the day of survey, 03/18/2025 at 9:15 am, the laboratory failed to produce documentation for theQA meetings conducted for 21 out of 21 months from May 2023 to February 2025 when MOHS micrographic surgery slide examinations were performed. 3. The TP confirmed the findings above on 03/18/2025 at 9:50 am.</p>
D6128	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.</p>

This STANDARD is not met as evidenced by:

Based on review of competency assessment (CA) records, and interview with the Testing Personnel (TP), the Technical Supervisor (TS) failed to assess the annual competency for 1 of 1 TP that performed histopathology examinations in 2024.

Findings Include: 1. On the day of survey, 03/18/2025 at 09:10 am, review of competency assessment records revealed the TS failed to assess the annual competency assessment for 1 of 1 TP for microscopic and macroscopic (grossing) histopathology examinations in 2024 2. The TP confirmed the findings above on 03/18/2025 at 09:50 am.