

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2179374	(X3) Date Survey Completed 10/24/2025
Name of Provider or Supplier Polaris Skin Diagnostics	Street Address, City, State 8170 Rourk St Suite 100, Myrtle Beach, SC	
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
D0000	An announced onsite recertification survey was conducted at Polaris Skin Diagnostics Laboratory on October 24, 2025. The facility was found to be out of compliance with the Medicare Condition at 42 CFR Part 493. Laboratory Requirements. The following STANDARD LEVEL DEFICINCIES were found to be out of compliance:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on testing personnel record review and testing personnel interview, the laboratory failed to assess the competency of two of three testing personnel (TP) performing high-complexity testing and general supervisor (GS) for 2025 as required (493.1413(b)(8)/ 493.1451(b)(8)). Findings included: 1. Review of personnel records revealed two out of three testing personnel due for an annual competency for 2025. 2. The surveyor requested the laboratory failed to provide competencies for the following testing employees: a. TP1 b. TP4/GS 3. It was confirmed during an exit interview at 3:12 pm on October 23, 2025, in the office with testing personnel/general supervisor that an annual competency assessment had not been performed.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each</p>

special stain must be documented.

This STANDARD is not met as evidenced by:

Based on policy and procedure review, and testing personnel interview, the laboratory failed to document the reactions of the control slide(s) with each special stain as required 493.1273. Findings included: 1. A review of policy/procedure for "Special Stain" reveals the lack of stating the necessity to document the control slide's reactivity. 2. During an exit interview at 12:12 pm on October 24, 2025, in the office with testing personnel/general supervisor the above findings were confirmed.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on procedure manual review, testing personnel record review, and testing personnel interview, the laboratory director/technical supervisor failed to ensure that competency assessments were performed annually as required for testing personnel and general supervisor performing high-complexity testing. Reference (D5209)