| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 10D2050274 | 11/21/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Phdermatology South Srq | 1545 Mound St, Sarasota, FL | |

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 CLIA recertification survey was conducted at S Mark Burnett MD PA on 11/21/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency: |
| **D5473** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(2)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview the laboratory failed to document test staining materials for intended reactivity for six of six testing days in November of 2024 for Hematoxylin & Eosin (H&E) slides. Findings included: Review of the November 2024 Daily H&E Quality Control Evaluation Form documented testing was performed 11/4/24, 11/6/24, 11/11/24, 11/13/24, 11/18/24 and 11/20/24. There was no documentation Testing Person # A had approved the Quality Control slide reactivity for each day of use. Review of the laboratory procedure manual, approved by the Laboratory Director on 9/17/2024, revealed a Quality Control and Quality Assurance Procedure, which documented "This procedure to be performed by all personnel within the scope of practice." Histology Tech #A confirmed on 11/21/2024 at 1:30 pm, the Laboratory Director (Testing Person #A) had not documented acceptable reactivity for six of six testing days in November of 2024 for H&E slides. |