

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2275745	<b>(X3) Date Survey Completed</b>  06/10/2025
<b>Name of Provider or Supplier</b>  Palm Harbor Dermatology, Pa DbA	<b>Street Address, City, State</b>  1801 South Osprey Avenue Ste #201, Sarasota, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Palm Harbor Dermatology PA DBA PHDermatology Sarasota on 06/10/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
<b>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview, the laboratory failed to identify errors on their accession log (Mohs Specimen Log) for one (06/2024) of three months (04/2025, 06/2024, and 10/2023) reviewed for the subspecialty of Histopathology. Findings included: 1. The Mohs Specimen Logs for 04/2025, 06/2024, and 10/2023 were reviewed. The June 2024 data indicated patient testing was performed on the 6th, 11th, 12th, and 20th. 2. Analytic records for June 2024 were reviewed. They included the following forms: Quality Control Slide for Hematoxylin and Eosin, Temperature Log for Room, Temperature Log for Cryostat, Hematoxylin and Eosin Stain Line Set-up Quality Control and Maintenance, Cryostat Maintenance, and Microscope Maintenance documented testing was performed on the 6th, 12th, 13th and 20th. 3. The Mohs Tech (who was acting on behalf of the Lab Director) was interviewed on 06/10/2025 at 12:15 p.m. They confirmed that testing was performed on 06/06, 06/12, 06/13 and 06/20 of 2024. 4. Three patients (#1 - #3) were selected for review. One from each month reviewed 04/2025, 06/2024, and 10/2023. The Mohs Specimen Log for patient #2, test performed 06/20/2024 indicated three slides were stained. 5. Observations of patient #2's stained slides revealed 4 slides. 6. The Mohs</p>

Tech (who was acting on behalf of the Lab Director) was interviewed on 06/10/2025 at 12:15 p.m. They confirmed the above, 4 and 5. 7. The Quarterly Quality Assurance Checklist for Quarter: April - June 2024, signed by Laboratory Director on 07/11/2024, was reviewed. The line "Specimens were logged correctly on the Mohs specimen log" was marked "Y" (Yes). 8. The Mohs Tech (who was acting on behalf of the Lab Director) was interviewed on 06/10/2025 at 12:15 p.m. They confirmed the lab failed to identify any of the discrepancies listed above.