

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D2104539	<b>(X3) Date Survey Completed</b>  03/16/2022
<b>Name of Provider or Supplier</b>  Dermio Dermatology	<b>Street Address, City, State</b>  9200 Calumet Ave Suite N203, Munster, IN	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow its stain validation procedures prior to patient testing for one of eight specialized stains (human herpes virus-8 (HHV-8)) reviewed and two of two patients (PT#11 - PT#12) reviewed with the HHV-8 stain performed. Findings include: 1. "VALIDATION FOR IMMUNOHISTOCHEMICAL STAINS", no effective date, requires that five known positive control must be stained to validate each stain. 2. "VALIDATION APPROVAL SHEET", dated 1/3/2022, for the HHV-8 stain indicated only two positive controls were performed. 3. "LAB ERROR AND CORRECTIVE ACTION FORM", dated 1/3/2022, indicated that not enough control tissue for the HHV-8 stain was available for validation. Additionally, the future prevention stated that the lab will "send T. Pallidum cases out to another lab". 4. On 03/15/2022 at 3:58 pm, SP1 acknowledged that positive controls for HHV-8 stain were on back-order and that the validation had two positive controls. 5. The "Special Stain Report" indicated that PT#11 and PT#12 was stained for HHV-8 on 02/10/2022 and 03/09/2022 respectively. 6. Annual test volume for the HHV-8 stain is approximately 2.</p>