

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2104539	(X3) Date Survey Completed 09/17/2020
Name of Provider or Supplier Dermio Dermatology	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to verify the accuracy of Mohs histology testing at least twice annually during two of two years reviewed (2018 and 2019). Findings included: 1. Review of policy/procedure titled: "Proficiency Testing," approved by the laboratory director on 10-25-2016, read: "Semi-annually, the tech or Risk Manager will send two cases containing the original slides, label it with only the surgical case number, and send it out for a microscopic examination by a Board Certified Dermatopathologist." 2. Review of proficiency testing (PT) documentation indicated the following: a. The laboratory verified the accuracy of Mohs histology slides once during 2018 (on 5-14-2018) b. The laboratory sent five Mohs histology slides from 2019 to another dermatopathologist. However, the review was completed on 9-16-2020. There was no documentation the laboratory verified the accuracy of Mohs histology testing during 2019. 3. Review of patient test reports indicted the following patients had Mohs histology testing performed: Patient #8 (2-7-2019) and Patient #12 (12-19-2019). 3. In interview on 9-17-2020 at 11:03 AM, SP1, Mohs Technician, acknowledged the laboratory sent five Mohs histology slides from 2019 to another dermatopathologist on 9-14-2020 and received the results from the review back on 9-16-2020. SP1 indicated the laboratory did not send any Mohs histology slides to another dermatopathologist for PT review in 2019. At 12:15 PM on the same date, SP1 acknowledged the laboratory sent Mohs histology slides to another dermatopathologist only once in 2018 for PT review. 4. Review of "Test Methodology And Annual Test Volume Log," (Enclosure I), indicated the laboratory performed 400 Mohs histology slides annually.</p>