

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2120705	<b>(X3) Date Survey Completed</b>  12/12/2018
<b>Name of Provider or Supplier</b>  Tarantola Dermatology Inc Fairhope	<b>Street Address, City, State</b>  411 N Section Street Suite 300, Fairhope, AL	
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>D5217</b>	<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 information obtained during the entrance tour, a review of the Procedure Manual and the "Proficiency Testing" (PT) documentation (used for accuracy verification of Histopathology processing and interpretation), and an interview with the Laboratory Director, the surveyor determined the Laboratory Director: (1) failed to ensure the Dermatologist reviewing the facility's results on four cases (from "2-11/2018") documented her findings, (2) failed to document an assessment and comparison of the peer groups' results with the laboratory's results for 13 of 13 2017-2018 cases, and (3) further failed to resolve a possible discrepancy noted in one of four January to May 2018 cases. The findings include: 1. During the entrance interview and tour of the laboratory at approximately 8:45 AM on 12/12/2018, the Histotechnologist stated the Laboratory Director read and interpreted the Histopathology slides from frozen sections on specimens from on-site MOHS Surgical Procedures. 2. A review of the procedure manual revealed the policy, "Proficiency Testing", which specified the laboratory would send out four slides semi-annually for independent review by Dermatopathologists in Pensacola, FL. 3. A review of the most recent PT documentation from "2-11/2018" revealed the list of four case numbers, and the diagnosis (SCC [Squamous Cell Carcinoma] or BCC [Basal Cell Carcinoma]), and Staining and Sectioning Quality for each case; the log also specified the Pensacola, FL Dermatopathologist to whom the slides were sent. The MOHS Maps for the four cases were attached to the log. 4. A review of the PT documentation from "Jan - May 2018" revealed the list of four case numbers, and the diagnosis, staining and Sectioning Quality for each case; the log also specified the Pensacola Dermatopathologist to whom the slides were sent. The MOHS Maps for the</p>

four cases were attached to the log. However, in these cases the Dermatopathologist had entered "P" (Positive) or N (Negative) in the Diagnosis column (as per the instructions on the form). 5. A review of all the 2017-2018 PT documentation revealed no indication of whether the Laboratory Director had reviewed the returned results (as indicated by her signature and date), and whether the outside Dermatopathologist's interpretations were comparable with the in-house laboratory results. 6. During an interview and review of the above records on 12/12/2018 at approximately 10:45 AM, the surveyor asked the Laboratory Director about the "2-11 /2018" PT records. The surveyor explained it was difficult to understand the PT process, and which of the slides the Dermatopathologist were reviewing when making the interpretations. The Director explained she brought all the slides from the four cases to Pensacola, FL, then the Dermatopathologist reviewed the slides and the two physicians discussed the findings. The surveyor then asked if the Pensacola Dermatopathologist had documented her findings; the Director confirmed she had not; the interpretations had only been discussed. 7. As the interview continued, the surveyor then reviewed records for the first case in the "Jan-May 2018" PT. The Pensacola Dermatopathologist had documented "P" for the diagnosis; the MOHS Map showed (+) for S (Stage) I, and (-) for S II. The surveyor asked about which slides the Dermatopathologist had reviewed, or if both stages were positive, meaning there was a discrepancy with the Director's results. The Director stated she did not know what the Dermatopathologist meant when she noted "P" for this particular case. 8. As the interview concluded, the surveyor asked the Laboratory Director if she documented her review of the returned results (as indicated by her signature and date), and whether the outside Dermatopathologist's interpretations were comparable with the in-house laboratory results, (such as no discrepancies, minor discrepancies with no effect on patient care, or major discrepancies which would require documentation of corrective action and resolution). The Director confirmed she had not been doing this, and had not understood all the CLIA requirements for performance and documentation of the Histopathology accuracy verification (PT). Thus the above noted findings were confirmed. Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor