

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2123092	<b>(X3) Date Survey Completed</b>  03/20/2019
<b>Name of Provider or Supplier</b>  Nash Dermatology Llc	<b>Street Address, City, State</b>  1935 East Glenn Ave Suite 101, Auburn, 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 MOHS Technician, the surveyor determined the Laboratory Director: (1) failed to ensure an assessment and comparison of the consulting SkinDx pathologist's results with the laboratory's results was documented for two of two 2017-2018 PT events, and (2) further failed to document his reviews (as indicated by a signature and date) for three of three of the PT results to determine if any corrective actions were required when the documents were returned. The findings include: 1. During the entrance interview and tour of the laboratory at approximately 9:30 AM on 3/21/2019, the MOHS Technician 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 laboratory's procedures revealed slides from two cases would be sent out for semi-annual review to dermatopathologists at SkinDx, and peer review at ASMS (American Society of MOHS Surgery). 3. A review of the PT documentation sent to SkinDx revealed to following: A) 9/6/2017: The PT form listed N17M-031 and N17M-422 as the cases sent out. The SkinDx pathologist documented his assessments of the Staining and Sectioning Quality, and interpretation of each of the individual slides. However, the facility had failed to document the Laboratory Director's original interpretations of the slides, and surveyor further noted a discrepancy in the case #'s; MOHS Maps were attached for Case # N17M-31 and N17M-74 (not -422). There was no indication this discrepancy had been noticed or resolved. B) 10/29/2018: The PT form listed N18M-257 and N18M-598 as the cases</p>

sent out. The SkinDx pathologist documented his assessments of the Staining and Sectioning Quality, and interpretation of I as "P" (Positive) and II as "N" (Negative). However, the facility had failed to document the Laboratory Director's original interpretations of the slides. A review of the above 2017-2018 PT documentation revealed no indication of whether the Laboratory Director had reviewed the returned results (as indicated by his signature and date), and whether the outside Dermatopathologist's interpretations were comparable with the in-house laboratory results. 5. A review of Case # 18168 sent out on 3/15/2018 to ASMS for peer review revealed no documentation of review of the returned assessment. 6. During an interview and review of the above records on 3/21/2019 at approximately 11:00 AM, the surveyor asked the MOHS Technician about the discrepancies in the 2017 PT Case #'s. The Technician stated it must have been an oversight since she was certain slides N17M-74 had been sent out as the PT case for review. 7. As the interview continued at approximately 11:05 AM, the surveyor asked the MOHS Technician if the Director documented review of the returned results (as indicated by a 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 Technician confirmed they 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. .

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1299(a)

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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:  
Based on a lack of post-analytical quality assurance documentation, a review of slides, MOHS maps and final results reports, and an interview with the MOHS Technician, the surveyor determined the laboratory failed to establish and implement a mechanism to monitor, assess, and correct problems noted in Histopathology documentation, specifically a discrepancy in one of five patient records. The findings include: 1. On 3/21/2019 at approximately 11:30 AM, the surveyor conducted a post-analytical random review of slides, MOHS maps and final results reports from five patients who had MOHS surgical procedures in 2017-2019. 2. A review of Case # N17M-398 revealed a diagnosis (Dx) of BCC (Basal Cell Carcinoma) in the MOHS patient log, and on the MOHS final patient report, however the MOHS Map (used by the physician when performing the procedure and reading the slides) listed a Dx of SCCIS (Squamous Cell Carcinoma In Situ). 3. During a review of the above patient records and an interview on 3/21/2019 at 12:10 PM, the MOHS Technician reviewed and confirmed the above noted discrepancy in the Dx on Case # N17M-398. When asked if the laboratory conducted "Chart Reviews", or had implemented another mechanism to ensure the accuracy of the patient records, the Technician stated they had not. Thus, the above noted findings were confirmed. SURVEYOR ID #32558  
Licensure and Certification Surveyor