

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1041974	(X3) Date Survey Completed 05/17/2018
Name of Provider or Supplier Princeton Dermatology Associates	Street Address, City, State 208 Bunn Drive, Princeton, NJ	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Clinical Consultant (CC), the laboratory failed to perform CA correctly on two out of two Testing Personnel in the calendar year 2016 and 2017. The findings include: 1. The laboratory did not document when TP were observed, what records were reviewed and how assessment was done. 2. TP #2 listed on CMS form 209 did not have a CA for the calendar year 2016. 3. The CC confirmed on 5/17/18 at 10:20 am that CA was not performed correctly.</p>
D5401	<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 surveyor review of the Procedure Manual (PM), Biannual Assessment Records (BR) and interview with the Clinical Consultant (CC), the laboratory failed to follow their Quality Control (QC) procedure for Biannual Assessment (BA) in the calendar year 2017. The finding includes: 1. The PM stated under QC Documentation</p>

6.1.3 "Twice a year 3 cases shall be sent out to an outside physician" but a review of the BR revealed that one case twice a year was sent for BA. 2. The CC confirmed on 5/17/18 at 10:10 am that the PM was not followed.

D5601

HISTOPATHOLOGY
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records, accession log and interview with the Testing Personnel (TP), the laboratory failed to record the reaction of a control slide for Hematoxylin and Eosin (HE) stains in September 2017. The finding includes: 1. A review of the accession log revealed that on 9/14/17 ten Mohs test were performed but the reaction of a HE QC was not documented. 2. The TP # 1 listed on CMS form 209 confirmed on 5/17/18 at 11:00 AM that QC was not documented on 9/14/17.