

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2110303	(X3) Date Survey Completed 03/13/2018
Name of Provider or Supplier Dermatology Physicians, Inc https://Web.Qiesnet.Org	Street Address, City, State 1613 Oregon Pike, Lancaster, PA	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on observation and review of procedure manuals, and interview with the Mohs Tech and a Registered Nurse (RN), the laboratory Director failed ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. Findings include: 1. On the date of survey, 03/13/2018, the Procedure manual reviewed at the time of inspection , revealed that the laboratory director has been delegating of procedure manuals for revisions and updates to one of the RN's. 2. The Procedure manual did not have the current laboratories director's signature and date of approval. 3. Appendix C states "Approval of procedures and changes to procedures is the responsibility of the laboratory director. This responsibility cannot be delegated." 4. The Mohs Tech and a Registered Nurse (RN), confirmed the finding above on 03/13/2018 around 03:00 PM.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on tour of Histology Laboratory and interview with the Mohs Tech and a Registered Nurse (RN), the laboratory failed to ensure that Tissue Marking Dye is not</p>

used beyond its expiration date. Finding Include: 1. On the Date of survey, 03/13/2018, during the tour of the Histology laboratory, 1 of 1 bottle of Yellow Avantik Tissue Marking Dye was discovered that expired 01/2018. 2. From the expiration date of the yellow tissue marking dye (01/2018) to the date of survey (03/13/2018), 331 slides were read. 2. The Mohs Tech and a Registered Nurse (RN) confirmed the findings above on 03/13/2018 around 02:45 PM.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on, the review of laboratory's quality control records, and interview with the Mohs Tech and a Registered Nurse (RN), the laboratory failed to perform quality control for potassium hydroxide (KOH) and wet mount microscopic examination from 2017 to the date of survey. Findings: 1. On the date of survey 03/13/2018, review of the laboratory's quality control records revealed that the the Laboratory Quality control form for KOH and Wet mounts review if the slide is intact and if the reagents are current but does not include the qualitative procedure, include a negative and positive control material (can be reference material). 2. Roughly 50 specimen were examined for KOH and Wet mount each year in 2016 and 2017. 3. The Mohs Tech and RN confirmed the findings above on 03/13/2018 around 03:30 PM.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:
Based on, the review of competency assessment records, peer review records and interview with the Mohs tech and a Registered nurse (RN) the Technical Consultant (TC) (Laboratory Director) failed to assess the competency of all Testing personnel through internal blind testing samples or external Peer review samples in 2017. Findings Include: 1. On the date of survey, 03/13/2018, review of competency assessment records and 2017 Histology peer review records revealed the TC did not assess test performance of 1 of 3 (TP#3) through internal blind testing samples, external PT, or peer review samples in 2017. 2. In 2017, 1273 specimen were read. 2. the Mohs tech and a RN confirmed the findings above on 03/13/2018 around 02:30 PM.