

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D1037117	<b>(X3) Date Survey Completed</b>  02/20/2019
<b>Name of Provider or Supplier</b>  Dermatopathology Consultants Llc	<b>Street Address, City, State</b>  104 White Horse Pike, Haddon Heights, NJ	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 lack of the Competency Assessment (CA) records, review of the personnel files and interview with the Technical Supervisor (TS), the laboratory failed to perform a CA on five out of five Testing Personnel (TP) in the calendar years 2017 and 2018. The findings include: 1. This deficiency was cited on survey report dated 3 /7/17. 2. The plan of corrections stated "CLIA competency information from CMS website is being reviewed and integrated into the lab's procedure manual. This will provide an accurate method for the director to evaluate. Projected implementation date June 2017" 3. The TS confirmed on 2/20/19 at 11:25 am that CA was not performed on TP.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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), visual observation of the staining station and interview with the Technical Supervisor (TS) the laboratory failed</p>

to follow its Hematoxylin and Eosin Stain Procedure from 3/7/17 to the date of the survey. The findings include: 1. The staining program in the Leica Auto Stainer XL (LAS) laboratory did not correspond with the staining procedure found in the PM. a. Step B in the PM stated to stain for 10 minutes but the LAS was programmed for 7 minutes. b. Step E & G in the PM stated to wash for 1 minute 30 seconds but the LAS was programmed for 1 minute. 2. The TS confirmed on 2/20/19 at 10:00 am the laboratory did not follow the PM.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:  
Based on surveyor observation of reagents and interview with the Technical Supervisor (TS), the laboratory failed to check the expiration date for reagents used for Histopathology tests on the date of the survey. The finding includes: 1) Fast Green 0.01% Aqueous was expired 3/3/18. 2) Approximately 10 patients were run and reported. 3) The TS confirmed on at 11:10 am that the laboratory had expired reagents.