

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1001532	<b>(X3) Date Survey Completed</b>  02/05/2018
<b>Name of Provider or Supplier</b>  University Park Dermatology	<b>Street Address, City, State</b>  8451 Shade Ave Ste 205, Sarasota, FL	
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>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 record review and interview with the Office Manager, the laboratory did not have competency evaluations on 1 out of 1 (#B) Testing Person for 2 out of 2 years (2016-2017) reviewed. Findings Included: Review of Testing Person #B's employee records revealed no competency evaluations. During an interview on 02/05/18 at 12:00 PM the Office Manager confirmed that no competency evaluations were performed on Testing Person #B.</p>
<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 record review and interview with the Office Manager, the laboratory failed to verify the accuracy of testing at least twice a year for 2 out of 2 (2016-2017) years reviewed. Findings Included: Review of verification of test accuracy for Histopathology revealed peer reviews conducted on 03/05/17 and 06/02/16. No other peer reviews were provided. During an interview on 02/05/18 at 11:44 PM the Office Manager confirmed that there were no other peer reviews conducted.</p>

<p><b>D5407</b></p>	<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 record review and interview with the Office Manager, the Laboratory Director failed to sign the procedure manual for approval when new policies were implemented in 2016. Findings Included: Review of the policy and procedure manual revealed that it was last signed by the Laboratory Director in 2015. During an interview on 02/05/18 at 12:55 PM the Office Manager confirmed that there were changes that were implemented in 2016 and that the Laboratory Director did not sign off on them as approved.</p>
<p><b>D5417</b></p>	<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 observation and interview with the Office Manager the laboratory had expired reagents in the laboratory since 07/13/17. Findings Included: During a tour of the laboratory on 02/05/18 at 9:30 PM it was observed that Scott Tap Water Substitute (Lot # 1635801) had an expiration date of 12/28/17 and Eosin Y Stain Solution 1% in Alcohol (Lot # 1519041) expired on 07/12/17. During an interview on 02/05/18 at 10:15 AM the Office Manager confirmed that the expired reagents have been used for testing because there were no other reagents to use.</p>
<p><b>D5429</b></p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observations and interview with the Office Manager the laboratory failed to perform preventative maintenance on 2 out of 2 microscopes for 1 (2017) out of 2 (2016-2017) years reviewed. Findings Included: During a tour of the laboratory on 02/05/18 at 9:30 AM two microscopes were observed with a preventative maintenance sticker on both that said it was performed on 10/12/16 and that it was due 04/12/17. There was no documentation of the preventative maintenance being performed in 2017. During an interview on 02/05/18 at 10:15 AM the Office Manager confirmed that the 2017 preventative maintenance had not been performed.</p>