

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2140678	(X3) Date Survey Completed 03/06/2018
Name of Provider or Supplier University Dermatology, Inc	Street Address, City, State 11590 North Meridian Street, #450, Carmel, IN	
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 document review and interview, the facility did not have written policies and procedures to assess ten of ten testing personnel. Findings Include: 1. Upon request for documentation of competency for testing personnel in subspecialties; Mycology, Parasitology, and Virology, none was available for review. 2. In interview on 3/6/18 at 10:30 am, SP#1 confirmed there were no policies/procedures regarding competency for testing personnel in the subspecialties; Mycology, Parasitology, and Virology.</p>
D5217	<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 document review and interview, the laboratory failed to twice annually verify the accuracy of testing performed in Histopathology, Mycology, Parasitology, and Virology for ten of ten testing personnel. Findings include: 1. Upon request for documentation of twice annual verification of accuracy for testing performed in Histopathology, Mycology, Parasitology, and Virology, none was provided. 2. In interview on 03/06/18 at 11:30 a.m., SP#1 confirmed the twice annual verification of</p>

accuracy had not been performed for Histopathology, Mycology, Parasitology, and Virology.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on document review and interview, the laboratory director failed to ensure a quality assessment program was established and maintained to ensure the quality of laboratory services provided in four of four testing area reviewed; Histopathology, Mycology, Parasitology and Virology. Findings include: 1. Upon request for documentation of a quality assessment program to ensure the quality of laboratory services provided, the laboratory director indicated a quality assessment program had not been established. 2. In interview on 03/06/18 at 12:00 p.m., SP#1 confirmed no quality assessment program had been established.