

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2134036	(X3) Date Survey Completed 11/05/2019
Name of Provider or Supplier Advanced Dermatology Pc	Street Address, City, State 37-51 82nd Street, Jackson Heights, NY	
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 a review of laboratory competency records and an interview with the regional manager, the laboratory failed to follow their written policies and procedures to assess the competency of the laboratory testing personnel semi-annually for the first year of patient testing. Findings Include: It was confirmed by the regional manager on November 5, 2019, at approximately 11:00 am, that the laboratory director acting as the technical consultant failed to have documentation of semi-annual competency for one of three testing personnel who performs fungal culture testing.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p>

	<p>This STANDARD is not met as evidenced by: Based on a review of personnel records and an interview with the regional manager, the laboratory director failed to have documentation of training for fungal culture testing. Findings Include: On November 5, 2019, at approximately 10:50 am, it was confirmed by the regional manager, that the director failed to ensure that appropriate training was documented for three of three testing personnel who perform moderate complexity testing for fungal culture testing.</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the regional manager, the laboratory director, acting as the technical consultant, failed to perform the semi-annual evaluation for three of three testing personnel performing fungal cultures during the first year of patient testing in the calendar year 2018. Refer to D5209.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on a review of personnel records and an interview with the regional manager, the laboratory director failed to ensure that one of three testing personnel performing moderate complexity testing met the minimum educational requirements of a high school diploma and/or had a foreign education diploma evaluated prior to performing patient testing. Refer to D6065</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and</p>

This STANDARD is not met as evidenced by:
Based on a review of personnel records and confirmed in an interview with the regional manager on November 5, 2019, at approximately 11:00 am, the laboratory director failed to ensure that the one of three testing personnel performing moderate complexity testing met the minimum educational requirements of a high school diploma and/or had a foreign education diploma evaluated prior to performing patient testing.