

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0989131	<b>(X3) Date Survey Completed</b>  08/14/2019
<b>Name of Provider or Supplier</b>  Meghan M Caruso Do	<b>Street Address, City, State</b>  875 Route 73 North, Suite D, Marlton, 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 and interview with the Testing Personnel (TPGS), the laboratory failed to perform a CA on one out of one TP from 8/16/17 to the date of survey. The TP # 2 listed on CMS form 209 confirmed on 8/14/19 at 10:20 am that CA was not performed on TP.</p>
<b>D6030</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(12)</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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Testing</p>

Personnel (TP), the Laboratory Director (LD) failed to establish a Competency Assessment (CA) procedure with the required elements from 8/16/17 to the date of the survey. The PT # 2 listed on CMS form 209 confirmed on 8/14/19 at 10:45 am that CA procedure was not established by LD.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Personnel Records (PF) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to specify in detail the duties and responsibilities for one out of one TP engaged in the performance of Dermatophye Test Media testing from 8/16/17 to the date of survey. The TP # 2 listed on CMS form 209 confirmed on 8/14/19 at 10:15 am that the LD did not specify the duties and responsibilities of TP.