

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 14D0418678	<b>(X3) Date Survey Completed</b> 08/22/2019
<b>Name of Provider or Supplier</b> Dermatology Associates	<b>Street Address, City, State</b> 18425 W Creek Dr, Ste F, Tinley Park, IL	
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 review of laboratory records and interview with the laboratory director (LD); the laboratory failed to establish policies and procedures to assess competency for personnel involved in microbiology testing. Findings Include: 1. Review of the laboratory's policy and procedure manual found no policy had been established to assess the competency of all personnel involved in dermatophyte test medium (DTM) cultures and potassium hydroxide (KOH) preparations. 2. On survey date 08-22-2019 at 3:30 pm, the LD confirmed the laboratory failed to establish a competency assessment policy for personnel involved in microbiology testing.</p>
<b>D5805</b>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p>

This STANDARD is not met as evidenced by:  
Based on review of laboratory records and interview with the laboratory director (LD); the laboratory's test reports failed to indicate the name and address where testing was performed for 5 of 5 pathology test reports reviewed. Findings Include: 1. Review of 5 of 5 patient test reports (Patient Identifiers: P6, P7, P8, P9, P10) for pathology testing failed to indicate the following: a. The name and address of the laboratory location where the grossing and interpretation of pathology slides was performed. 2. During survey date on 8-22-2019, at 3:30 pm, the above findings were confirmed by the LD.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on review of laboratory records and interview with the laboratory director (LD); the technical consultant (TC) failed to ensure competency of testing personnel (TP) was complete in 2017 through the date of survey in 2019 for 4 of 4 moderate complexity testing personnel listed on the CMS-209 (Laboratory Personnel Report). Findings Include: 1. Review of the laboratory's policy and procedure manual failed to identify a competency assessment policy for personnel performing dermatophyte test medium (DTM) cultures and potassium hydroxide (KOH) preparations. See D5209. 2. Review of the laboratory manual found copies of a form titled, "Competency Assessment By Direct Observation", which had been partially completed. The form identified the procedures DTM cultures and KOH preparations and indicated that performance was acceptable and the employee was competent to perform the procedures, however the space for employee name was left blank. 3. Review of competency assessment records found the partially completed form, "Competency Assessment By Direct Observation" used for the competency assessments for 3 of the testing personnel (TP#5, TP#7, and TP#8), listed on the CMS-209 laboratory personnel report in 2017, 2018, and 2019. 4. Further review of the competency assessment records in 2017, 2018 and 2019 revealed that the competency assessments for DTM cultures and KOH preparations failed to address the follow: a. Monitoring the recording and reporting of test results. b. Review of intermediate test results or worksheets, quality control records, proficiency testing records, and preventative maintenance records. c. Assessment of test performance through internal blind samples or proficiency testing samples. d. Assessment of problem solving skills 5. Review of competency assessment records found no competency assessments were completed for TP#6. 6. On survey date 8-22-2018, at 3:30 pm the LD confirmed the direct observation competency assessment form had been filled out prior to the competency assessments of TP#5, TP#7, and TP#8 in 2017 through 2019 and failed to cover all six elements of competency. Additionally, no competency assessments had been completed for TP#6.

**D6063**

**LABORATORY TESTING PERSONNEL**  
CFR(s): 493.1421

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.

This CONDITION is not met as evidenced by:

Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to employ testing personnel (TP) who meet the qualification requirements of 493.1423. Findings Include: 1. TP#6, as listed on the CMS-209 (Laboratory Personnel Report), failed to have documented training prior to analyzing patient specimens for moderate complexity dermatophyte test medium (DTM) cultures. See D6066.

**D6066**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to have training documentation for 1 of 1 new moderate complexity testing personnel (TP) performing dermatophyte test medium cultures (DTM) prior to patient testing. Findings Include: 1. Review of laboratory personnel records found no training documentation for TP#6, as listed on the CMS-209 (Laboratory Personnel Report) prior to analyzing patient specimens for dermatophyte test medium (DTM) cultures. 2. On survey date 08-22-2019, at 3:30 pm, the LD confirmed the laboratory failed to have training documentation for TP#6 prior to analyzing patient specimens.

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the laboratory director (LD); the laboratory director failed to review 6 of 8 microbiology proficiency testing (PT) reports in 2017 through 2019. Findings Include: 1. Microbiology proficiency testing records were reviewed for 2017 through 2019. 2. Review of American Proficiency Institute (API) proficiency testing records revealed the LD failed to review API PT results for the following PT events: a. Microbiology event 2 of 2019 b. Microbiology event 3 of 2018 c. Microbiology event 2 of 2018 d. Microbiology event 1 of 2018 e. Microbiology event 3 of 2017 f. Microbiology event 2 of 2017 3. On survey date 8-22-19, at 3:30 pm, the surveyor findings were confirmed by the LD.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on review of laboratory records and interview with the laboratory director (LD); the laboratory director failed to specify, in writing, the responsibilities and duties for all personnel engaged in the preanalytic, analytic, and postanalytic phases of testing for microbiology and pathology. Findings Include: 1. Review of the laboratory policy and procedure manual revealed the LD failed to specify, in writing, the responsibilities and duties of each person engaged in the performance of testing for dermatophyte test medium (DTM) cultures, potassium hydroxide (KOH) preparations and pathology testing. 2. On survey date 08-22-2019 at 3:30 pm, the LD confirmed the laboratory failed to specify, in writing, the responsibilities and duties for all the personnel involved in the testing.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:  
Based on review of laboratory records and interview with the laboratory director (LD); the technical supervisor (TS) failed to complete annual competency assessments for 1 of 2 high complexity testing personnel performing the grossing of pathology specimens. Findings Include: 1. Competency assessment records were reviewed for 2 of 2 testing personnel performing the grossing of pathology specimens. 2. Review of the competency assessment records revealed the annual competency assessments in 2018 and 2019 for testing personnel (TP) #2, as identified on the CMS-209 (Laboratory Personnel Report), failed to cover the grossing of pathology specimens. 3. On survey date 8-22-2019, at 3:30 pm, the LD confirmed that annual competency assessments in 2018 and 2019 for TP#2 failed to cover the grossing of pathology specimens.