

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D1028878	<b>(X3) Date Survey Completed</b>  08/13/2019
<b>Name of Provider or Supplier</b>  Academic Dermatology & Cosmetic Surgery Center	<b>Street Address, City, State</b>  51189 Shelby Pkwy, Shelby Township, MI	
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:</p> <ul style="list-style-type: none"> <li>. Based on procedure review, record review, and interview with the office manager and a staff member, the laboratory failed to ensure written competency policies were established and implemented that included the six procedural requirements from subpart M for two (August 2017 to August 2019) of two years of mycology testing. Findings include: 1. Procedure review of the "CLIA/Lab Book" revealed the laboratory did not have a competency policy that included the six procedural requirements from subpart M as follows: a. "Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; b. Monitoring the recording and reporting of test results; c. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; d. Direct observations of performance of instrument maintenance and function checks; e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and f. Assessment of problem solving skills." 2. Record review of competency assessments revealed a lack of documentation for two (August 2017 to August 2019) of two years for the assessments of the mycology potassium hydroxide (KOH) testing as follows: a. annual testing (2017 - 2019) for testing personnel #1 and #2. b. six month and 12 month (2018) for testing personnel #3. 3. During the interview on August 13, 2019 at 10:35 am, the office manager and office staff member confirmed the "CLIA/Lab Book" lacked a competency policy and a lack of documentation for the assessments for two years for testing personnel #1 - #3.</li> </ul>

**D5601**

**HISTOPATHOLOGY**

CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the office manager and office staff member, the laboratory failed to document the onsite professional interpretation of the hematoxylin & eosin (H&E) differential stain quality for nine (K-65027, K-36235, K-10455, I-89595, I-41951, I-72703, I-26751, I-09164, and H-96472) of nine dermatopathology cases reviewed. Findings include: 1. Record review from the off-site processing facility revealed the stain quality for positive and negative reactivity of the H & E stain was observed and documented for the dates of the nine random cases reviewed. 2. On August 13, 2019 at 11:10 a.m., the surveyor requested documentation for the on-site H & E stain interpretation for the professional component of the slide review. The lab was unable to provide the surveyor the documentation requested for nine of nine cases reviewed as follows: a. K-65027 b. K-36235 c. K-10455 d. I-89595 e. I-41951 f. I-72703 g. I-26751 h. I-09164 i. H-96472 3. During the interview on August 13, 2019 at 11:10 a.m., the office manager and office staff member confirmed the professional component of the stain quality interpretation was not documented.

**D5787**

**TEST RECORDS**

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

. Based on record review and interview with the office manager and office staff member, the laboratory failed to maintain a record system that 1) included the case number recorded on the final Mohs' map for ten (17-54, 17-77, 18-05, 18-29, 18-61, 18-96, 19-01, 19-20, 19-37, and 19-58) of ten Mohs' cases and 2) include the specimen receipt time into the laboratory for each stage level of testing for six (17-54, 18-05, 18-61, 19-01, and 19-20) of ten Mohs' cases reviewed. Findings include: 1. Record review for ten of ten Mohs' cases reviewed the laboratory failed to include the case identification (ID) number on the final Mohs' map as follows: a. 17-54 b. 17-77 c. 18-05 d. 18-29 e. 18-61 f. 18-96 g. 19-01 h. 19-20 i. 19-37 j. 19-58 2. Record review for six of ten Mohs' cases reviewed the laboratory failed to include the time of receipt into the laboratory for processing on each stage level on the final Mohs' map as follows: a. 17-54 - no time for levels #1-#3 b. 18-05 - no time for level #2 c. 18-29 - no time for level #2 d. 18-61 - no time for level #2 e. 19-01 - no time for levels #1-#4 f. 19-20 - no time for levels #1-#2 3. During the interview on August 13,

2019 at approximately 11:00 a.m., the office manager and office staff member confirmed the final Mohs' map in the patients chart did not contain the Mohs' case ID and stage level receipt times.