| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>26D1098985 | (X3) Date Survey Completed<br>08/30/2021 |
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| **Name of Provider or Supplier**<br>Nichols Mohs And Skin Surgery | **Street Address, City, State**<br>303 N Keene St, Ste 201, Columbia, MO | |

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 |
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| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency records for 2019/2020 and interview with testing personnel (TP) #2, the laboratory failed to establish a means to verify the accuracy of potassium hydroxide (KOH) microscopic examination testing twice a year. Findings: 1. Review of proficiency records for 2019 and 2020 showed the laboratory failed to prove accuracy on the non-regulated analyte for KOH microscopic exams twice yearly. 2. Interview with TP #2 on August 25, 2021 at 8:30 AM confirmed the laboratory failed to verify the accuracy of the non-regulated KOH microscopic exam testing twice annually. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of histopathology procedures and interview with testing personnel (TP) #2, the laboratory failed to have a written procedure for potassium hydroxide (KOH) microscopic examination. Findings: 1. Review of procedures showed no procedure for potassium hydroxide (KOH) microscopic examination. 2. Interview |

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| | with TP #2 on August 25, 2021 at 8:30 AM confirmed the laboratory could not provide a written procedure for potassium hydroxide (KOH) microscopic examination. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Thermo Scientific Cryostat Microm HM 525 operator's guide, lack of temperature and humidity logs and interview with testing personnel (TP) #2, the laboratory failed to follow manufacturer's instructions for monitoring and documenting temperature and humidity. Findings: 1. Review of the Thermo Scientific Cryostat Microm HM 525 operator's guide states "Operating conditions: +5 degrees C up to +35 degrees C (at a max rel. humidity of 60%)". 2. Lack of temperature logs confirmed no documentation of temperature and humidity in 2019, 2020 and to date August 25, 2021. 3. Interview with GS on August 25, 2021 at 8:30 AM confirmed the laboratory failed to follow manufacturer's instructions for monitoring and documenting temperature and humidity. |
| **D6102** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(12)<br><br>The laboratory director must 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of testing personnel (TP) training documents and interview with the laboratory director (LD), the LD failed to ensure two of two TP received the appropriate training before performing patient testing. Findings: 1. Lack of TP training documents showed TP #2 and TP #3 had no documented training before patient testing was performed. 2. Interview with the LD on August 25, 2021 at 9:00 AM confirmed the LD failed to ensure TP #2 and TP #3 received the appropriate training before performing patient testing. |
| **D6127** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(9)<br><br>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. |

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| | This STANDARD is not met as evidenced by:<br>Based on lack of performance evaluations and interview with the laboratory director (LD), the technical supervisor (whom is also the LD) failed to evaluate and document performance evaluations at least semiannually during the first year for two of two testing personnel (TP). Findings: 1. Lack of performance evaluations showed no semiannual performance evaluations were documented during the first year of patient testing for TP #2 and TP #3. 2. Interview with the LD on August 25, 2021 at 9:00 AM confirmed the technical supervisor did not evaluate and document the semiannual performance evaluation for TP #2 and TP #3. |
| **D6128** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(9)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of performance evaluations and interview with the laboratory director (LD), the technical supervisor (whom is also the LD) failed to evaluate and document annual performance evaluations for two of two testing personnel (TP) in 2020. Findings: 1. Review of performance evaluations showed no annual performance evaluation for TP #2 and TP #3 in 2020. 2. Interview with the LD on August 25, 2021 at 9:00 AM confirmed the technical supervisor failed to evaluate and document annual performance evaluation for TP #2 and TP #3 in 2020. |