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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 31D0123439 | (X3) Date Survey Completed 01/24/2018 |
| Name of Provider or Supplier Kuflik Dermatology Center | Street Address, City, State 453 Lakehurst Rd, Toms River, NJ | |
| 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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| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to have Operator's Manual (OM) for Shandon Linistain GLX slide stainer from 12/22/15 to the date of survey. The TP # 6 confirmed on 12/24/18 at 10:00 am that the OM was not available.</p> |
| D5433 | <p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory records and interview with the Testing Personnel (TP), the laboratory failed to establish a maintenance protocol for the stainer when protocols were not provided by the manufacturer from 12/22/15 to the</p> |

date of survey. The TP # 6 listed on CMS form 209 confirmed on 1/24/18 at 10:20 am that the laboratory did not establish maintenance protocol.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

The laboratory director must 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.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the applicable elements for Mohs technician from 12/22/15 to the date of survey. The TP # 6 listed on CMS form 209 confirmed on 1/24/18 at 10:30 am that a CA procedure was not established.