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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 31D2160690 | (X3) Date Survey Completed 12/13/2021 |
| Name of Provider or Supplier Henning Dermatology Group | Street Address, City, State 175 Morristown Road, Basking Ridge, 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 |
|---------------------------|---|
| D5403 | <p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Office Manager (OM) the laboratory failed to have all applicable procedures for Histopathology tests from 7/25/19 to the date of the survey. The finding includes: 1. The laboratory did not have a procedure for slide retention. 2. The OM confirmed on 12/13/21 at 10:15 am that the PM did not have all applicable procedures.</p> |
| D5407 | <p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> |

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to have an approved, signed and dated PM by the LD from 7/25/19 to the date of the survey. The OM confirmed on 12/13/21 at 10:00 am a PM signed by the LD was not available.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

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.

This STANDARD is not met as evidenced by:

Based on surveyor review of the lack of Temperature Records (TR) and interview with the Office Manager (OM), the laboratory failed to document Room Temperature (RT) where Histopathology test reagents were stored and tests were performed from 7/25/19 to the date of the survey. The findings include: 1. There were no temperatures recorded. 2. The OM confirmed on 12/13/21 at 9:45 am that the laboratory failed to accurately record RT.

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 surveyor review of the Accession Log (AL), Mohs slides, final report and interview with the Office Manager (OM), the laboratory failed to maintain accurate record system for Mohs testing from 7/25/19 to the date of survey. The finding includes: 1. Accession # 22061821 had three slides recorded in the AL but the laboratory had two slides 2. Accession # 12091120 had two slides recorded in the AL but the laboratory had three slides 3. The OM confirmed on 12/13/21 at 10:15 am that the laboratory failed to have an accurate record system.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

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.

This STANDARD is not met as evidenced by:

Based on surveyor review of Personnel Records (PR) and interview with the Office Manager (OM), the Laboratory Director failed to ensure that the education records were available for all Testing Personnel (TP) on the date of the survey. The finding includes: 1. Education records were not available for one out of two TP. 2. The OM confirmed on 12/13/21 at 9:30 am that education records were not available.