| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 46D2013546 | 01/13/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Granger Medical Clinic Dermatology | 9001 S 3200 W, Unit 2, West Jordan, UT | |

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** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on procedure manual review, lack of a procedure and interview with staff, the laboratory lacked a step by step procedure for performing and recording the gross analysis for histopathology testing. The laboratory performed approximately 1500 histopathology biopsy and excisions per year. Findings include: 1. Procedure manual review failed to include the process for grossing and recording the measurements and description of the specimen. 2. The laboratory failed to record the gross analysis for Mohs surgical specimen 19-237. 3. In an interview conducted on 01/13/2021 at approximately 10:50 A.M., staff confirmed the procedure manual failed to include the |

| | |
|---|---|
| | grossing process from measurement to description and recording of the surgical specimen or biopsy.. |
| **D5787** | TEST RECORDS<br>CFR(s): 493.1283(a)<br><br>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).<br><br>This STANDARD is not met as evidenced by:<br>Based on patient test records review, lack of documentation, and interview with the director, the laboratory failed to retain initial biopsy test results for specimens the laboratory referred for confirmation from January 2019 to 2021. The number of biopsy specimens referred for confirmation was not determined. Findings include: 1. Patient test record review included review of the biopsy test log . A. Specimen # 51319 for patient date of birth (DOB) 06/09/1944 of a Right anterior Medial deltoid was selected for review. The laboratory lacked documentation of the initial diagnosis made by the laboratory retaining the reference laboratory diagnosis of Squamous Cell Carcinoma and Basal Cell Carcinoma - nodular. B. Specimen #82868 for patient DOB 10/20/1954 from a lipoma on the upper back. The laboratory lacked documentation of the initial diagnosis made by the laboratory prior to the consult diagnosis of benign by the reference laboratory. 2. In an interview conducted on 01/13/2021 at approximately 11:30 A.M. the director confirmed the laboratory removed test records for the initial diagnosis of specimens sent for consultation to prevent confusion. |