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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 23D2021984 | (X3) Date Survey Completed 12/21/2021 |
| Name of Provider or Supplier Clarkston Dermatology | Street Address, City, State 5701 Bow Pointe Drive Suite 215, Clarkston, MI | |
| 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 |
|---------------------------|---|
| D5301 | <p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD), the laboratory failed to have a electronic request for patient testing from an authorized person for 1 (#19) of 20 patient charts audited. Findings include: 1. Record review revealed for 1 (#19) of 20 patient charts audited the laboratory did not have an electronic request for laboratory testing by an authorized person for the dermatophyte test media (DTM) testing completed on 8/26/2021. 2. An interview on 12/21/2021 at 11:59 am, the LD confirmed the patient testing did not have an electronic request.</p> |
| D5801 | <p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with the Laboratory Director (LD), the</p> |

laboratory failed to establish a system to ensure the transcribed Mohs' surgical site were accurately reported on the Mohs' map and in the laboratory information system (LIS) for 1 case (796) of 15 Mohs' cases reviewed from December 2019 to December 2021. Findings include: 1. Record review revealed for 1 case (796 performed on 12/30/2019) of 15 Mohs' cases reviewed, the Mohs' surgical site on the Mohs' map and in the LIS system did not match the original Pathology report location. 2. An interview on 12/21/2021 at 12:14 pm, the LD confirmed the locations on the Mohs' map and in the LIS system were not consistent with the original Pathology report.

D5803

TEST REPORT
CFR(s): 493.1291(b)

Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:
. Based on record review, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to have the final dermatophyte test media (DTM) patient test report maintained as part of patients' electronic medical record (EMR) for 1 (#19) of 20 patient charts reviewed. Findings include: 1. On 12/21/2021 at approximately 12:00 pm, the surveyor requested 20 test orders and reports maintained in the patients' EMR system. 2. A record review revealed for 1 (#19) of 20 patient charts reviewed a lack of documentation in the patient's EMR for the DTM performed on 8/26/2021. 3. An interview on 12/21/2021 at 11:59 am, the LD confirmed the patient testing was not available in the patient's EMR and not made available to the surveyor.