

|  |  |   |
|--|--|---|
| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>46D0706479 | <b>(X3) Date Survey Completed</b><br><br>01/22/2020 |
| <b>Name of Provider or Supplier</b><br><br>Dmb Medical   | <b>Street Address, City, State</b><br><br>1385 E 750 N, Orem, UT           |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
|---------------------------|--|
| <b>D5805</b>              | <p>TEST REPORT<br/>CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on test records reviewed, test reports reviewed, specimen slide review and interview with the laboratory manager, the laboratory failed to include the specimen case number on the test report for Mohs frozen section test reports and failed to include the biopsy slide number on the formalin fixed paraffin embedded (FFPE) histopathology specimens report for 15 of 15 reports reviewed. The laboratory reported approximately 3370 histopathology test results per year. Findings include: 1. A. Test records reviewed for Mohs frozen section histopathology cases included the case numbers: J18-18, J18-64, J19-20, J19-103, and J19-104 on the Mohs surgical map and the slides from the frozen section included the case numbers on the slide as the unique identification of the specimens. Specimens J19-103 and J19- 104 were from the same patient. B. Test records for skin biopsies included the patient's name and slide number in the laboratory specimen log book. 2. Specimen slides reviewed included the patient's name and case number for frozen sections and the patient's name and slide number for the FFPE slides. 3. Test reports reviewed failed to include the case number in the surgical pathology reports for frozen section cases and failed to include the slide number on skin biopsy histopathology reports. 4. In an interview conducted on 01/22/2020 at approximately 4:40 P.M. staff confirmed the test reports</p> |

did not include the case number for frozen section or the slide number for shave or punch biopsy histopathology as positive identification of the specimen reported.