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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>23D2232085       | <b>(X3) Date Survey Completed</b><br><br>08/03/2022 |
| <b>Name of Provider or Supplier</b><br><br>Memorial Healthcare Dermatology   | <b>Street Address, City, State</b><br><br>802 W King Street, Suite G, Owosso, MI |   |
| 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>   |
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| <b>D5401</b>              | <p>PROCEDURE MANUAL<br/>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:</p> <p>A. Based on record review and interview with the Laboratory Director (LD), the laboratory failed to follow its "Specimen Handling, Storage, Transport, Preservation and Identification" procedure for 2 (OMH22-008 and OMH22-023) of 8 days of performing the Mohs' procedure. Findings include: 1. A review of the laboratory's "Specimen Handling, Storage, Transport, Preservation and Identification" procedure revealed on step 7 "Slides are labeled with accession number (OMHyear-xxxx), last name of patient, first initial, location of surgery being done, stage number in the bottom left corner of slide (I,II,III), and slide number L1, L2, L3) in bottom right." 2. A review of the laboratory slides on 8/03/2022 at 11:10 am, revealed for cases OMH22-008 to OHM22-023 a lack of location of the surgery being done on the processed slides. 3. An interview on 8/03/2022 at 12:30 pm, the LD confirmed the Mohs' slides did not contain the surgery location as stated in the procedure. B. Based on record review and interview with the Office Manager (OM), the laboratory failed to establish and implement a procedure for the sending out of Mohs' cases/slides for review for 3 (June to August 2022) of 3 months of operation. Findings include: 1. A review of Mohs' cases revealed the slides for cases OMH22-0001 and OMH22 -006, were not available on the day of the survey as they had been sent to an outside facility for review. 2. When queried on 8/03/2022 at 12:00 pm, the OM stated that the laboratory did not have a log or means to track the sent out cases other than a hand</p> |

written sticky note posted on the inside of a binder. 3. A interview of 8/03/2022 at 12: 30 pm, the OM confirmed the laboratory did not establish and/or implement a procedure for sending slides to outside facilities.