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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 44D2231464 | (X3) Date Survey Completed 07/02/2024 |
| Name of Provider or Supplier Heritage Medical Associates | Street Address, City, State 325 Old Pleasant Grove Road, Mount Juliet, TN | |
| 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 |
|---------------------------|---|
| D5417 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation, patient test records, and staff interviews, the laboratory failed to ensure that it did not use four of four lots of tissue marking dyes beyond their expiration in micrographically oriented histographic surgery (Mohs) histopathology patient testing. The findings include: 1. Observation of the Mohs laboratory on 07/02/2024 at 8:10 a.m. revealed the following opened Avantik tissue marking dyes: - Green (lot: 121757) with an expiration date of 5/31/2023 - Yellow (lot: 118666) with an expiration date of 3/31/2023 - Black (lot: 122217) with an expiration date of 5/31/2023 - Blue (lot: 121983) with an expiration date of 5/31/2023 2. A review of random review of patient records revealed the laboratory performed Mohs testing on 06/28/2023 (Case M23-029), 11/28/2023 (Case M23-169), 02/21/2024 (Case M24-057), and 06/18/2024 (Case M24-196). 3. An interview with the histotechnician on 07/02/2024 at 11:30 a.m. confirmed that the laboratory used the observed tissue marking dyes for patient testing (including the four cases reviewed) after expiration.</p> |