

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0968114	(X3) Date Survey Completed 01/10/2023
Name of Provider or Supplier Christopher M Lowther Md	Street Address, City, State 802 Gerrans Ave, Cody, WY	
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 observation, review of the Mohs surgery log sheet, and staff interview, the laboratory failed to ensure staining reagents were not used beyond their expiration date for 1 of 1 procedure (Mohs surgery histopathology). The findings were: 1. Observation on 1/10/23 at 8:30 AM showed one bottle of Avanti Gill 3 hematoxylin stain had a received date of 3/3/21; an open date of 11/9/21; and an expiration date of 6/20/22. 2. Review of the Mohs surgery log sheet showed 64 Mohs procedures had been performed from 7/1/22 through 1/9/23. 3. Interview with the Mohs technician on 1/10/23 at 9:04 AM confirmed the hematoxylin stain was expired.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on medical record review, staff interview, and review of the quality control (QC) log sheet and "Daily Routine" policy, the laboratory failed to ensure the</p>

hematoxylin and eosin stains were tested for their intended reactivity and the results documented for 4 of 6 Mohs cases (22M-054, 22M-055, 22M-056, 22M-057) reviewed. The laboratory performed approximately 213 Mohs surgery cases per year. The findings were. 1. Review of the medical record for Mohs case 22M-054 showed 4 stages of tissue had been examined for malignant cells on 4/28/22. Review of the QC log sheet showed no evidence the hematoxylin and eosin stains had been tested for the appropriate reactions. 2. Review of the medical record for Mohs case 22M-055 showed 3 stages of tissue had been examined for malignant cells on 4/28/22. Review of the QC log sheet showed no evidence the hematoxylin and eosin stains had been tested for the appropriate reactions. 3. Review of the medical record for Mohs case 22M-056 showed 1 stage of tissue had been examined for malignant cells on 4/29/22. Review of the QC log sheet showed no evidence the hematoxylin and eosin stains had been tested for the appropriate reactions. 4. Review of the medical record for Mohs case 22M-057 showed 3 stages of tissue had been examined for malignant cells on 4/29/22. Review of the QC log sheet showed no evidence the hematoxylin and eosin stains had been tested for the appropriate reactions. 5. Review of the "Daily Routine" policy showed "...3. Run QC and log any lot numbers or changes made..." 6. Interview with the Mohs technician on 1/10/23 at 9:04 AM confirmed the results of the QC performed on the stains had not been documented.