

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D0933802	<b>(X3) Date Survey Completed</b>  10/13/2022
<b>Name of Provider or Supplier</b>  Patrick M Hatfield M D , P A	<b>Street Address, City, State</b>  299 Eagle Mountain Blvd, Batesville, AR	
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>D5435</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Through a review of the Mohs Surgery Logs for December 2021 and May 2022, a review of Temperature Monitor Logs for December 2021 and May 2022, and interviews with laboratory staff, it was determined the laboratory failed to document cryostat temperatures on two of three days of use in December 2021 and six of six days of use in May 2022. Survey findings include: A. Through a review of the Mohs Surgery logs for December 2021 and May 2022 it was determined the laboratory performed Mohs Surgery on 12/8/2021 (1 patient), 12/14/2021 (5 patients), 12/28/2021 (3 patients), 5/3/2022 (5 patients), 5/10/2022 (6 patients), 5/11/2022 (1 patient), 5/17/2022 (5 patients), 5/24/2022 (6 patients), and 5/31/2022 (7 patients). B. During a review of the Temperature Monitor Logs for December 2021 and May 2022, it was revealed the laboratory failed to document cryostat temperatures on 12/14/2021 (3 patients tested), 12/28/2021 (3 patients tested), 5/3/2022 (5 patients tested), 5/10/2022 (6 patients tested), 5/11/2022 (1 patient tested), 5/17/2022 (5 patients tested), 5/24/2022 (6 patients tested), and 5/31/2022 (7 patients tested). C. In an interview at 11:13 a.m. on 10/13/2022, laboratory employee #2 (as listed on the form CMS-209) confirmed that the cryostat temperature was not documented on 8 days of testing in December 2021 and May 2022.</p>

**D5473**

**CONTROL PROCEDURES**

CFR(s): 493.1256(e)(2)(g)

(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.

This STANDARD is not met as evidenced by:

Through a review of the Mohs Surgery Log for December 2021, a review of the "Quality Control Log: Daily Worksheet" for December 2021, and through interviews with laboratory personnel, it was determined the laboratory failed to perform quality control of the Hematoxylin and Eosin (H and E) stain on one of three days of use in December 2021. Survey findings include: A. A review of the Mohs Surgery Log for December 2021 showed Mohs surgery cases documented on 12/8/2021, 12/14/2021, and 12/28/2021 with three patient Mohs surgeries performed on 12/28/2021. B. A review of the "Quality Control Log: Daily Worksheet" for December 2021 revealed that the last documented quality control of the H and E stain was on 12/15/2021. Documentation was not available for one of three days when patient Mohs surgeries were performed. C. In an interview at 11:13 a.m. on 10/13/2022, laboratory employee #2 (as listed on the form CMS-209) confirmed that stain quality control was not documented on 12/28/2021 when three patients had Mohs surgeries documented.