

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0888204	<b>(X3) Date Survey Completed</b> 05/11/2022
<b>Name of Provider or Supplier</b> Matthew J Rowley Md	<b>Street Address, City, State</b> 107 Christie Street, Lufkin, TX	
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>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, patient result logs for KOH and Mohs, and confirmed in an interview found the laboratory failed to monitor the expiration dates for two of five reagents available for use. The findings were: 1. The surveyor's director observation on 5/11/22 at 9:25 am in the lab revealed two of five reagents available for use were expired. Frozen Embedding Media for Mohs Lot: 90113 Exp: 12/21 Potassium Hydroxide 10% in DMSO for KOH Lot: 0043 Exp: 2022-02-12 2. Review the patient Mohs result logs from 1/4/22 to 5/10/22 revealed 46 patients were performed Mohs procedure. 1/4/22 Case# MMSR2204382 Case# MMSR2204383 1/11/22 Case# MMSR2204384 1/25/22 Case# MMSR2204385 Case# MMSR2204386 Case# MMSR2204387 1/27/22 Case# MMSR2204388 2/8/22 Case# MMSR2204389 Case# MMSR2204390 2/15/22 Case# MMSR2204391 Case# MMSR2204392 Case# MMSR2204393 Case# MMSR2204394 Case# MMSR2204395 Case# MMSR2204396 2/22/22 Case# MMSR2204397 Case# MMSR2204398 3/1/22 Case# MMSR2204399 Case# MMSR2204300 Case# MMSR2204401 Case# MMSR2204402 3/8/22 Case# MMSR2204403 Case# MMSR2204404 Case#</p>

MMSR2204405 Case# MMSR2204406 3/15/22 Case# MMSR2204407 Case# MMSR2204408 Case# MMSR2204409 Case# MMSR2204410 3/22/22 Case# MMSR2204411 3/29/22 Case# MMSR2204412 Case# MMSR2204413 Case# MMSR2204414 Case# MMSR2204415 4/5/22 Case# MMSR2204416 Case# MMSR2204417 Case# MMSR2204418 4/12/22 Case# MMSR2204419 4/19/22 Case# MMSR2204420 4/26/22 Case# MMSR2204421 Case# MMSR2204422 Case# MMSR2204423 Case# MMSR2204424 5/3/22 Case# MMSR2204425 5/10/22 Case# MMSR2204426 Case# MMSR2204427 3. An interview with the office manager on 5/11/21 at 9:30 am in the lab confirmed the above finding.

**D5601**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's policy, QC logs, patient result logs from 4/20/21 to 5/10/22, and confirmed in an interview found the laboratory failed to document stain QC acceptability for 27 of 27 days for one of one stains: H&E Stain. The findings were: 1. Review of the laboratory's policy revealed no stain QC acceptability policy. 2 Review of the laboratory's QC logs revealed no QC logs available. 3. Random review of patient result logs from 4/20/21 to 5/10/22 revealed no documentation of stain QC acceptability for H&E stain by surgeon/pathologist for 27 of 27 days. 4/20/21 4/27/21 5/11/21 6/29/21 7/27/21 8/3/21 8/17/21 8/24/21 8/31/21 9/7/21 9/28/21 10/26/21 11/2/21 11/9/21 11/17/21 11/19/21 11/30/21 12/14/21 12/21/21 1/4/22 1/11/22 1/25/22 1/27/22 2/8/22 2/15/22 2/22/22 3/1/22 3/8/22 3/15/22 3/22/22 3/29/22 4/5/22 4/12/22 4/19/22 4/26/22 5/3/22 5/10/22 4. Review of patient result logs for the above dates revealed 76 patients with stain slides. 4/20/21 Case# MMSR2104352 4/27/21 Case# MMSR2104353 Case# MMSR2104354 5/11/21 Case# MMSR2104355 6/29/21 Case# MMSR2104356 7/27/21 Case# MMSR2104357 8/3/21 Case# MMSR2104358 8/17/21 Case# MMSR2104359 Case# MMSR2104360 8/24/21 Case# MMSR2104361 8/31/21 Case# MMSR2104362 9/7/21 Case# MMSR2104363 Case# MMSR2104364 9/28/21 Case# MMSR2104365 10/26/21 Case# MMSR2104366 Case# MMSR2104367 Case# MMSR2104368 11/2/21 Case# MMSR2104369 11/9/21 Case# MMSR2104370 Case# MMSR2104371 Case# MMSR2104372 11/17/21 Case# MMSR2104373 11/19/21 Case# MMSR2104374 11/30/21 Case# MMSR2104375 Case# MMSR2104376 Case# MMSR2104377 12/14/21 Case# MMSR2104378 Case# MMSR2104379 Case# MMSR2104380 12/21/21 Case# MMSR2104381 1/4/22 Case# MMSR2204382 Case# MMSR2204383 1/11/22 Case# MMSR2204384 1/25/22 Case# MMSR2204385 Case# MMSR2204386 Case# MMSR2204387 1/27/22 Case# MMSR2204388 2/8/22 Case# MMSR2204389 Case# MMSR2204390 2/15/22 Case# MMSR2204391 Case# MMSR2204392 Case# MMSR2204393 Case# MMSR2204394 Case# MMSR2204395 Case# MMSR2204396 2/22/22 Case# MMSR2204397 Case# MMSR2204398 3/1/22 Case# MMSR2204399 Case# MMSR2204300 Case# MMSR2204401 Case# MMSR2204402 3/8/22 Case# MMSR2204403 Case# MMSR2204404 Case# MMSR2204405 Case# MMSR2204406 3/15/22 Case# MMSR2204407 Case#

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Case# MMSR2204420 4/26/22 Case# MMSR2204421 Case# MMSR2204422 Case#  
MMSR2204423 Case# MMSR2204424 5/3/22 Case# MMSR2204425 5/10/22 Case#  
MMSR2204426 Case# MMSR2204427 5. An interview with the office manager on 5  
/11/22 at 11:16 am in the lab confirmed the above findings. Key: QC=Quality Control  
H&E=Hematoxylin & Eosin