

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2111077	<b>(X3) Date Survey Completed</b>  10/21/2022
<b>Name of Provider or Supplier</b>  John Chapman, Llc	<b>Street Address, City, State</b>  120 Rue Betancourt, Thibodaux, LA	
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>	A Recertification survey was performed on October 21, 2022 at John Chapman, LLC, CLIA ID # 19D2111077. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5401</b>	<p>PROCEDURE MANUAL 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: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to have a complete retention policy for slides utilized for Histopathology testing. Findings: 1. Review of the laboratory's "Storage" policy revealed "Mohs' slides will be stored on site for 7 years then be discarded in biohazard," not ten (10) years as required. 2. Review of the laboratory's "Mohs Surgery" policy, approved by the Laboratory Director on June 12, 2021, revealed "All medical records and slides are stored for 7 years and all materials are easily retrievable." 3. In interview on October 21, 2022 at 10:36 am the histotech confirmed the laboratory's policy for storage of Mohs slides did not include ten (10) years as required.</p>
<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)</p>

Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of logs, and interview with personnel, the laboratory failed to label marking dyes stored in secondary containers with the identity, expiration date, and applicable storage information. Findings: 1. Observation by surveyor during the laboratory tour on October 21, 2022 at 10:15 am revealed four (4) unlabeled vials of marking dyes. 2. Review of the laboratory's " 2022 Labeling of a Permanent Secondary Bottle Quality Check" log revealed documented performance January 2022 through October 2022. 3. In interview on October 21, 2022 at 10:36 am the histotech confirmed the secondary vials were not labeled identifying the content, lot number and expiration date.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of logs, and interview with personnel, the laboratory failed to ensure supplies did not exceed expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on October 21, 2022 at 10:15 am revealed the following expired items: a) Ferric subsulfate, Lot 8135, Expiration Date: 2020-05-15, Quantity: one (1) bottle b) Skin Pathology 10% Neutral buffered formalin, Lot 072222, Expiration Date: 2021-12-01, Quantity: six (6) containers 2. Review of the laboratory's records revealed a monthly "Lab Reviewed for Expired Items" log with documented checks January 2022 through October 2022. 3. In interview on October 21, 2022 at 10:36 am the histotech confirmed the identified items were expired.

**D5805**

TEST REPORT  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of random selection of patient test reports, quality assessment logs, and interview with personnel, the laboratory failed to ensure the address of the laboratory performing the test was included on the patient test report for one (1) of six (6) patients reviewed. Findings: 1. Review of the laboratory's "Mohs Quality

	<p>Assessment Three charts Bi-annually" log for 2022 revealed the laboratory reviewed three (3) charts biannually which included a review of patient demographic, site, surgery date, chart and laboratory diagnosis. 2. Review of random selection of patient test reports revealed the test report (visit note) for Case Number: CH22-326 on October 7, 2022 included the address of their other location, not the laboratory that performed the testing. 3. In interview on October 21, 2022 at 11:54 am the histotech stated for the identified patient the incorrect testing location was selected. The histotech confirmed the testing location's address was not included on the identified patient's test report.</p>
<p><b>D6087</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to label marking dyes stored in secondary containers with identity, expiration date, and storage requirements. Refer to D5415. 2. The laboratory failed to ensure supplies did not exceed expiration dates. Refer to D5417.</p>
<p><b>D6098</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(8)</p> <p>The laboratory director must ensure that reports of test results include pertinent information required for interpretation.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure final reports included required pertinent information. Refer to D5805.</p>
<p><b>D6106</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5401.</p>