Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2111077	08/30/2024
Name of Provider or Supplier	**Street Address, City, State**	
John Chapman, Llc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Recertification survey was performed on August 30, 2024 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.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and twice a year verification records and interview with personnel, the laboratory failed to verify the accuracy of Histopathology testing twice per year for two (2) of three (3) times as required. Findings: 1. Review of the laboratory's "Quality Control" policy under section "Independent Slide Quality Control-Bi-annually" revealed "Bi-annually, 5 patients are randomly selected and all slides from that patient's case/cases for that particular day are sent to Dermpath Diagnostic, Atlanta for diagnosis and accuracy." 2. Review of the laboratory's twice per year verification records revealed the laboratory did not have documentation of the verification of the accuracy of Histopathology testing for the second half of 2023 and the first half of 2024. 3. In interview on August 30, 2024 at 9:50 a.m., the Laboratory Director confirmed the twice per year verification was not performed as identified above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's

	instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on observation, review of manufacturer's instructions, and interview with personnel, the laboratory failed to follow the manufacturer's storage requirements for reagents. Findings: 1. Observation by surveyor during the laboratory tour on August 30, 2024 at 8:47 a.m. revealed the following reagents stored in an unlocked cabinet and not stored in a fire safety cabinet: a) StatLab Eosin-Y Alcoholic 0.25% 1 gallon - Quantity: One (1), Manufacturer's storage requirements: "Keep container tightly closed in a fireproof place." 2. In interview on August 30, 2024 at 10 a.m., Histotechnician 1 stated the laboratory did not have a flammable safety cabinet. She confirmed the reagents identified above were not stored in a fireproof place. II. Based on review of patient test records and laboratory temperature logs as well as interview with personnel, the laboratory failed to document the room temperature of the laboratory where supplies and the cryostat were located for six (6) of fourteen (14) days reviewed. Findings: 1. Review of the laboratory's patient logs revealed the laboratory performed patient testing on the following dates: - March 31, 2023 - April 14, 2023 - April 21, 2023 - April 28, 2023 - May 19, 2023 - May 26, 2023 2. Review of the laboratory's 2023 and 2024 temperature logs revealed the laboratory did not document the room temperature of the laboratory on the following dates: - March 31, 2023 - April 14, 2023 - April 21, 2023 - April 28, 2023 - May 19, 2023 - May 26, 2023 3. In interview on August 30, 2024 at 10:09 a.m., the Laboratory Director confirmed the room temperature of the laboratory was not documented on the dates identified above. III. Based on review of patient test records and laboratory temperature logs as well as interview with personnel, the laboratory failed to document the temperature of the cryostat for one (1) of seven (7) days reviewed. Findings: 1. Review of patient test logs revealed the laboratory utilized the cryostat on April 12, 2024 for patient specimens 172 - 185. 2. Review of the laboratory's temperature records revealed the laboratory did not document the temperature of the cryostat on April 12, 2024. 3. In interview on August 30, 2024 at 10:09 a.m., the Laboratory Director confirmed the cryostat temperature was not documented as identified above.
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: *** Repeat deficiency from previous follow-up survey performed on October 21, 2022.*** Based on observation and interview with laboratory personnel, the laboratory failed to ensure supplies did not exceed their expiration dates in one (1) of one (1) rooms where supplies are stored. Findings: 1. Observation by surveyor during the laboratory tour on August 30, 2024 at 8:47 a.m. revealed the following expired items: a) StatLab 10% Neutral buffered formalin specimen transport container - Lot: 112625, Expiration date: 12/31/2023, Quantity: Fifteen (15) b) StatLab 10% Neutral

	buffered formalin specimen transport container - Lot: 111374, Expiration date: 11/30 /2023, Quantity: One (1) 2. In interview on August 30, 2024 at 8:57 a.m., the Laboratory Director confirmed the supplies identified above were expired.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and patient test records as well as interview with personnel, the laboratory failed to ensure the quality assessment monitors in place identified issues within the postanalytic system. Findings: 1. Review of the laboratory's "Quality Control Policy" under the section "Mohs Log book and Note Quality Assessment" revealed "Each week the histotech will review all cases from the preceding week. The histotech will make sure the log book, original path, note and mohs map are in congruence for: 1. Name 2. Date of Birth 3. Site 4. Surgery Date 5. Surgeon 6. Chart Diagnosis 7. Laboratory Diagnosis 8. Accession Number 9. Location. If there is a discrepancy an addendum will be made. This will be documented weekly. The log will be stored at the physician's microscope ensuring the task is documented." 2. Review of the laboratory's patient log book, Moh's maps, and patient final reports for a random selection of seven (7) patients from November 2022 through July 2024 revealed the following one (1) patient had an incorrect last name on the Mohs map: a) April 21, 2023 - Case 145: Log book and patient final report both have the same last name for the patient, but the Mohs map had a different last name. 3. In interview on August 30, 2024 at 9:45 a.m., Histotechnician 1 confirmed the last name on the patient's driver's license matched the last name in the log book and final report. She confirmed the last name on the Moh's map was incorrect.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to verify the accuracy of Histopathology testing twice per year for two (2) of three (3) times as required. Refer to D5217. 2. The laboratory failed to follow the manufacturer's storage requirements for reagents. Refer to D5413 I. 3. The laboratory failed to document the room temperature of the laboratory where supplies and the cryostat were located for six (6) of fourteen (14) days reviewed. Refer to D5413 II. 4. The laboratory failed to document the temperature of the cryostat for one (1) of seven (7) days reviewed. Refer to D5413 III. 5. The laboratory failed to ensure supplies did not exceed their expiration dates in one (1) of one (1) rooms where supplies are stored. Refer to D5417.

D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5893.