Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2173230	06/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
John Chapman, Llc	101 Rue Fontaine Bldg 4, Lafayette, 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 June 18, 2024 at John Chapman, LLC, CLIA ID # 19D2173230. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies, twice year verification records, and interview with personnel, the laboratory failed to ensure the Quality Assessment (QA) monitors in place identified issues in the general laboratory system. Findings: 1. Review of the laboratory's "Quality Control" policy 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 verification records for 2023 revealed the laboratory sent slides from the second half of the year, but did not have documentation to support sending slides for review the first half of 2023. 3. In interview on June 17, 2023 at 12:09 p.m., the Lead Histotechnician stated she sent slides for review from the first half of the year in October 2023 and went on maternity leave before the slides were returned. She further stated in January 2024, after her return from leave, she noticed the slides along with the referral laboratory's review were not sent back, and in March of 2024, she reached out to the other laboratory to have them returned.

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 the laboratory's temperature records and manufacturer's instructions for use, as well as interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturer's required ranges for one (1) of one (1) rooms where reagents are stored. Findings: 1. Observation by the surveyor during the laboratory tour on June 17, 2024 at 10:18 a.m. revealed the laboratory stored the following reagents in the laboratory: a) Mercedes Medical Platinum Line Tissue Marking Dye Red - Manufacturer's storage requirements 20 - 30 degrees Celsius b) Mercedes Medical Platinum Line Tissue Marking Dye Blue - Manufacturer's storage requirements 20 - 30 degrees Celsius 2. Review of the laboratory's 2024 "Ambient Temperature and Humidity Control Check" log revealed the laboratory defined the acceptable temperature limits as 18 - 35 degrees Celsius which exceeded the manufacturer's acceptable upper and lower limits. 3. In interview on June 17, 2024 at 12:26 p.m., the Lead Histotechnician confirmed the laboratory's room temperature limits exceeded the limits of the manufacturer. II. 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 June 17, 2024 at 10:18 a.m. revealed the following reagents stored in an unlocked cabinet below the slidestainer and not stored in a fire safety cabinet: a) StatLab Eosin-Y Alcoholic 0.25% - Quantity: Three (3), Manufacturer's storage requirements: "Store locked up in a secure well-ventilated place. Keep container tightly closed in a fireproof place." 2. In interview on June 17, 2024 at 1 p.m., the Lead Histotechnician confirmed the reagents identified above were not stored in a fireproof place.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) 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. This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the laboratory failed to establish and label expiration dates for marking dyes. Findings: 1. Observation by surveyor during the laboratory tour on June 17, 2024 at 10:18 a.m. revealed the following open and in use marking dyes in their original primary containers: a) Mercedes Medical Platinum Line Tissue Marking Dye Red b) Mercedes Medical Platinum Line Tissue

	Marking Dye Blue 2. Further observation revealed the marking dye bottles identified above did not have expiration dates marked on each container. 3. In interview on June 17, 2024 at 11:00 a.m., the Lead Histotechnician confirmed the laboratory did not establish expiration dates for the marking dyes 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: Based on observation, review of expired items log, and interview with personnel, the laboratory failed to ensure that all laboratory reagents were not used beyond their expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on June 17, 2024 at 10:18 a.m. revealed the following expired items: a) Polarstat Plus Green Frozen Embedding Medium - Lot: 110784, Expiration date: 6/30/2023, Quantity: One (1) - Lot: 142102, Expiration date: 12/31/2023, Quantity: Four (4) b) Yellow Tissue Marking Dye - Lot: 123411, Expiration date: 6/30/2023, Quanity: One (1) c) Gill 2 Hematoxylin - Lot: 147707, Expiration date: 10/31/2023, Quantity: One (1) d) Submount Mounting Media - Lot: 1145, Expiration date: 5/25/2022, Quantity: One (1) e) Polarstat Plus Yellow - Lot: 150463, Expiration date: 5/31/2024, Quantity: Two (2) f) Polarstat Plus Blue - Lot: 144961, Expiration date: 3/31/2024, Quantity: One (1) g) Xylene Substitute - Lot: 150906, Expiration date: 5/31/2024, Quantity: Three (3) 2. Review of the laboratory's 2024 expired items log revealed a monthly check was documented for each month from January through June 2024. 3. In interview on June 17, 2024 at 11 a.m., the Lead Histotechnician stated personnel perform a monthly check for expired items. She confirmed the items listed above were expired.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 (Laboratory Personnel Report), laboratory policies, quality control records and test menu; as well as interview with personnel, the laboratory failed to ensure testing personnel signed the quality control logs indicating performance of stain quality assessment for Hematoxylin and Eosin (H&E) staining in 2023 and 2024. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Laboratory Director serves as the Testing Personnel for Mohs (Histopathology). 2. Review of the laboratory's "Quality Control" policy revealed "A daily quality control is done each surgery day. The first slide of the day is evaluated by the physician to make sure staining and microtomy are acceptable." 3. Review of the laboratory's "Mohs Daily Quality Control Slide Log" revealed laboratory personnel documented the assessment of the slide quality; however, the Laboratory Director did not document his assessment of the quality

	control. 4. In interview on June 17, 20224 at 12:33 p.m., the Lead Histotechnician stated she checks the slides for quality and documents the acceptability, but the Laboratory Director does not document his review of the quality control slide. 5. Review of the laboratory's test menu revealed the laboratory performs 2000 Mohs tests annually.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, review of temperature logs, and interview with personnel, the laboratory failed to perform corrective actions when the cryostat temperature exceeded acceptable limits for two (2) of one hundred eighty-one (181) days reviewed. Findings: 1. Observation by the surveyor during the laboratory tour on June 17, 2024 at 10:18 a.m. revealed two Leica CM 15105 cryostats in use. 2. Review of the laboratory's 2023 and 2024 "Cryostat Temperature Control Check" logs revealed the laboratory defined the acceptable temperature limits for the cryostat as -15 to -26 degrees Celsius. 3. Further review of the logs revealed the cryostat temperature exceeded the acceptable limits on the following days, but the laboratory did not perform corrective actions: a) Cryostat 545106-2006 January 16, 2023: -27 degrees Celsius March 21, 2023: -27 degrees Celsius 4. In interview on June 17, 2024 at 12:45 p.m., the Lead Histotechnician stated the temperatures were taken before the instruments were used for the day and once in use, the temperatures were in range. She confirmed the laboratory did not perform corrective actions for the temperatures as identified above.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies and records review and interview with personnel, the laboratory's quality assessment (QA) monitors failed to identify and correct quality issues in the analytic systems. Findings: 1. The laboratory failed to ensure that all laboratory reagents were not used beyond their expiration dates. Refer to D5417. 2. The laboratory failed to ensure testing personnel signed the quality

	control logs indicating performance of stain quality assessment for Hematoxylin and Eosin (H&E) staining in 2023 and 2024. Refer to D5609. 3.The laboratory failed to perform corrective actions when the cryostat temperature exceeded acceptable limits for two (2) of one hundred eighty-one (181) days reviewed. Refer to D5781.
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 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 define acceptable room temperature limits within the manufacturer's required ranges for one (1) of one (1) rooms where reagents are stored. Refer to D5413 I. 2. The laboratory failed to follow the manufacturer's storage requirements for reagents. Refer to D5413 II. 3. The laboratory failed to establish and label expiration dates for marking dyes. Refer to D5415. 4. The laboratory failed to ensure that all laboratory reagents were not used beyond their expiration dates. Refer to D5417.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 control program was maintained to assure the quality of laboratory testing. Refer to D5609.
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. Findings: 1. The laboratory failed to ensure the Quality Assessment (QA) monitors in place identified issues in the general laboratory system. Refer to D5293. 2. The laboratory's quality assessment (QA) monitors failed to identify and correct quality issues in the analytic systems. Refer to D5793.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.