Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2173230	01/25/2021
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	An Initial survey was performed on January 25, 2021 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.
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: Based on direct observation by surveyor and interview with personnel, the laboratory failed to properly store reagent grade alcohol as required by the manufacturer. Findings: 1. Direct observation by surveyor on January 25, 2021 at 1:07 pm revealed the ACS Grade dehydrant 100 % Reagent Alcohol (Lot # 078525, Quantity one (1) box and Lot # 087014, Quantity four (4) boxes) were stored in a cabinet. The boxes indicated "flammable." The identified 100% Reagent Alcohol bottles were not stored in a flammable storage cabinet. 2. In interview on January 25, 2021 at 3:00 pm the Laboratory Director confirmed the identified reagent grade alcohol was stored in a cabinet, not a flammable storage cabinet.
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 direct observation by surveyor and interview with personnel, the laboratory failed to label marking dyes stored in secondary containers with identity, expiration date, and storage requirements. Findings: 1. Direct observation by surveyor during laboratory tour on January 25, 2021 at 1:07 pm revealed the following marking dyes stored in unlabeled plastic bottles: a) One (1) container of red dye b) One (1) container of blue dye c) One (1) container of green dye 2. In interview on January 25, 2021 at 1:07 pm, the Histotechnician stated the marking dyes are poured into the bottles. The Histotechnician confirmed the identified secondary containers were not labeled with its contents.
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 direct observation by surveyor and interview with personnel, the laboratory failed to ensure laboratory supplies and reagents did not exceed their expiration dates. Findings: 1. Direct observation by surveyor during laboratory tour on January 25, 2021 at 12:54 pm revealed the following expired items: a) Platinum line Tissue Marking Dye Blue, Lot 50124, Quantity: one (1) bottle, Expiration date: 06/18 b) Platinum line Tissue Marking Dye Blue, Lot 65291, Quantity: one (1) bottle, Expiration date: 12/19 c) Platinum line Tissue Marking Dye Red, Lot 51126, Quantity: one (1) bottle, Expiration date: 04/17 d) Platinum line Tissue Marking Dye Red, Lot 65292, Quantity: one (1) bottle, Expiration date: 12/19 e) Shandon Eosin, Lot 363460, Quantity: one (1) bottle, Expiration date 02/2018 f) StatFix, Lot 6273, Quantity: two (2) bottle, Expiration date: 2018-09-29 g) PolarStat Plus Frozen Embedding Medium, Lot 050370, Quantity: one (1) bottle, Expiration date: 11/18 h) Trichloracetic Acid (TCA) solution, Lot K16AA, Quantity: one (1) bottle, Expiration date: October 2018 i) Clinical Laboratory Reagent Water Deionized Water, Lot 067499, Quantity: one (1) bottle, Expiration date: 06/20 j) StatLab Xylene Substitute, Lot 067586, Quantity: seven (7) bottles, Expiration date: 2019/06/01 k) StatLab Xylene Substitute, Lot 056782, Quantity: one (1) bottle, Expiration date: 08/19 l) StatLab Acetone, Lot 076812, Quantity: three (3) bottles, Expiration date: 2020-03-01 m) StatLab Acetone, Lot 069008, Quantity: one (1) bottle, Expiration date: 2020-03-01 2. In interview on January 25, 2021 at 1:02 pm, the Histotechnician confirmed the identified items were expired.
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: Based on review of the laboratory's policies and procedures, quality control logs, patient log book,and interview with personnel, the laboratory failed to perform quality control for Hemotoxylin and Eosin stain each day of patient testing for one (1) of ten (10) random dates selected from February 2020 through January 2021. Findings: 1. Review of the laboratory's "Quality Control" policy under "Slide Quality Control-Daily" section 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." 2. Review of the laboratory's "Mohs Daily Quality Control Slide Log" revealed the laboratory did not perform quality control assessment of stain quality for July 15, 2020. 3. Review of the laboratory's patient log book revealed the laboratory reported the following seven (7) patients without performing quality control: July 15, 2020: Case 749 Case 750 Case 751 Case 752 Case 753 Case 754 Case 755 4. In interview on January 25, 2021 at 2:03 pm, the Histotechnician confirmed the laboratory did not have documented performance of quality control for July 15, 2020.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of the laboratory's patient log book, patient Moh's maps, patient final reports, and interview with personnel, the laboratory failed to ensure a correct Histopathology result was reported for one (1) of twenty two (22) random selection of patients reviewed from February 2020 through January 2021. Findings: 1. Review of the laboratory's patient log book, Moh's maps, and patient final reports for random selection of twenty two (22) patients from February 2020 through January 2021 revealed the following one (1) patient had an incorrect result reported: September 30, 2020: Case 1064, Patient surgical Moh's map and the laboratory's patient log book indicated "BCC" as the tumor type. The patient's final report (Visit notes) indicated the tumor type/diagnosis as "Squamous Cell Carcinoma (SCC)." 2. In interview on January 25, 2021 at 2:52 pm, the Histotechnician stated the identified patient's visit notes/final report diganosis was incorrect. The Histotechnician confirmed the identified patient's Moh's map diagnosis and log book entry did not match the final report.
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 policies and procedures, patient test records and final reports, and 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 "Chart Quality Assessment" revealed "Biannually, 3 Mohs patients are randomly selected to be evaluated for quality control. The chart is opened in EMR and the diagnosis is recorded on the Assessment Sheet. The Lab diagnosis is obtained from the Mohs Lab Log and recorded on the Assessment Sheet. The following criteria are recorded on the Assessment Sheet: Name, Date of Birth, Site, Surgery Date, Surgeon, Repair, Chart Diagnosis, Laboratory Diagnosis. If the chart diagnosis does not match the lab diagnosis, the slide will be sent back for the original dermatopathologist for re-review. If the diagnosis is incorrect in the EMR, an addendum is recorded." 2. Review of the laboratory's patient log book, patient Moh's maps, patient final reports, and interview with personnel, the laboratory failed to ensure a correct Histopathology result was reported for one (1) of twenty two (22) random selection of patients reviewed from February 2020 through January 2021. Refer to D5821. 3. In interview on January 25, 2021 at 2:52 pm, the Histotechnician stated the laboratory reviews three (3) random cases twice a year by comparing the Moh's map, log book, and visit notes. The Histotechnician confirmed the laboratory's current quality assessment monitor was unable to identify the reporting issue within the postanalytic system.
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 direct 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 properly store reagent grade alcohol as required by the manufacturer. Refer to D5413. 2. the laboratory failed to label marking dyes stored in secondary containers with identity, expiration date, and storage requirements. Refer to 5415 3. The laboratory failed to ensure laboratory supplies and reagents did not exceed 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 D5473.
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.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. 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 D5821.