Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2105915	11/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Southwest Histology, Llc	3418 Midcourt Road, Suite 118-A, Carrollton, TX	

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 entrance conference was held 11/15/2019 with the Satellite Lab Manager (testing person -5). The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 11/15/2019, this facility was found NOT to be in compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.1487 - Laboratories performing high complexity testing; testing personnel An exit conference was held on 11/15/2019 with the Satellite Lab Manager (testing person -5) and the Histotechnologist (testing person - 4). The exit conference attendees were advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. An opportunity for questions and comments was provided.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on direct observation and review of maintenance records, the laboratory failed to retain annual preventive maintenance (PM) records for all equipment serviced used for histopathology procedures for 2018 and 2019. Findings included: 1. During a tour of the laboratory on 11/15/2019 at 12:15 pm, the following random sampling of equipment was observed with PM stickers for 2019: Tissue-Tek DRS 2000 automatic slide stainer - "ORION; [X] ELECTRIC SAFETY CHECK; [X] PREVENTATIVE MAINTENANCE; DATE: 5/6/19; INIT [initials]." Tissue-Tek TEC - "ORION; [X] ELECTRIC SAFETY CHECK; [X] PREVENTATIVE MAINTENANCE; DATE: 5/6 /19; INIT [initials]." H2850 Microwave Processor - "ORION; [X] ELECTRIC SAFETY CHECK; [X] PREVENTATIVE MAINTENANCE; DATE: 5/6/19; INIT [initials]." Leica RM2125/Leica RM2125 RT rotary microtome - "ORION; [X]

	ELECTRIC SAFETY CHECK; [X] PREVENTATIVE MAINTENANCE; DATE: 5/6 /19; INIT [initials]." During an interview on 11/15/2019 at 12:15 pm, testing person-4 (TP-4) and TP-5 were asked for the PM documentation performed by the company "ORION." The laboratory was unable to provide documentation. 2. The laboratory did not obtain/retain annual preventive maintenance (PM) records for all equipment serviced used for histopathology procedures for at least 2 years.
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 review of manufacturer's instructions, humidity logs, and in interview with staff, the laboratory failed to ensure their defined humidity was consistent with Sakura Tissue-Tek DRS 2000 and Tissue-Tek Autowrite Cassette printer manufacturer's operating condition requirements for 4 of 4 months in 2018 and 3 of 3 months in 2019 (random sampling: 06/2018, 07/2018, 08/2018, 09/2018, 08/2019, 09/2019, and 10 /2019). Findings included: 1. Review of Sakura Tissue-Tek DRS 2000 automatic slide stainer operator's manual (manufacturer's instructions) stated, "Specifications: Operating Conditions: Relative Humidity - 30% to 85% (noncondensing)." Review of Tissue-Tek Autowrite Cassette printer operator's manual (manufacturer's instructions) stated, "Components and Specifications: Operating Conditions: Relative Humidity: 30-80% (non-condensing)." 2. Review of a random sampling of laboratory's temperature /humidity charts from 06/2018, 07/2018, 08/2018, 09/2018, 08/2019, 09/2019, and 10 /2019 included a defined humidity of 20-60%, exceeding the lower end of the range for the equipment mentioned above (30%). The laboratory did not ensure their defined humidity was consistent with the manufacturer's. 3. During the exit interview on 11/15 /2019 at 2:30 pm, TP-4 and TP-5 reviewed and confirmed the above findings.
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 and in interview with staff, the laboratory used tissue marking dyes for histopathology procedures that had exceeded their expiration dates. Findings included: 1. During a tour of the laboratory on 11/15/2019 at 12:15 pm, the following in-use expired bottles of Tissue Marking Dyes by StatLab were observed to be stored underneath the hood where grossing occurs: Red Tissue Marking Dye - Lot #057801, EXP: 08/19 Violet Tissue Marking Dye - Lot #053480, EXP: 04/19 Green Tissue Marking Dye - Lot #056590, EXP: 08/19 Orange Tissue Marking Dye - Lot

	#055688, EXP: 09/19 Black Tissue Marking Dye - Lot #058084, EXP: 09/19 Yellow Tissue Marking Dye - Lot #058287, EXP: 0919 Blue Tissue Marking Dye - Lot #058369, EXP: 09/19 2. During an interview on 11/15/2019 at 12:15 pm, TP-4 and TP-5 reviewed and confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, maintenance records, and in interview with staff, the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency for the Sakura Tissue-Tek DRS 2000 and Leica RM 2125 Rotary Microtome for 12 of 12 months in 2018 and 2019. Findings included: 1. Review of Sakura Tissue-Tek DRS 2000 automatic slide stainer operator's manual (manufacturer's instructions) stated, "Section 6: Monthly Maintenance: Drying Station: The drying station should be cleaned once a month or more often as needed" follows by step-by-step instructions for cleaning. Review of Leica RM 2125 Rotary Microtome operator's manual (manufacturer's instructions) stated, "6.2 Maintenance instructions: Once a month, lubricate the following components with oil no. 405 (part of standard delivery. 1 to 2 are sufficient:" followed by a list and image of parts that should be oiled. 2. Review of maintenance records from 2018 and 2019 did not include documentation of cleaning the drying station and lubricating the microtome monthly, as required. 3. During an interview on 11/15/2019 at 12:15 pm, TP-4 was asked if the drying station was cleaned monthly for the Tissue-Tek DRS 2000 automatic slide stainer, he stated no. TP-4 was asked if monthly lubrication was done for the Leica RM 2125 Rotary Microtome, he stated its only lubricated when annual PM (preventive maintenance) is done. TP-4 and TP-5 reviewed and confirmed the above findings.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CMS 209 form, personnel records, and in interview with staff, the laboratory failed to ensure individuals employed met qualification requirements for high complexity testing. The laboratory failed to provide documentation of education to determine whether 1 of 5 testing persons (TP-4) met requirements to perform high complexity testing (grossing). Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of

osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

	Based on review of the CMS 209 form, personnel records, and in interview with staff, the laboratory failed to provide documentation of education to determine whether 1 of 5 testing persons (TP-4) met requirements to perform high complexity testing (grossing). Findings included: 1. Review of the CMS 209 form listed TP-4 as performing high complexity testing (histopathology grossing). 2. Review of personnel records for TP-4 included diplomas that were "Bachelors of Science" and "Associates of Applied Science." It could not be determined whether those degrees were in a chemical, physical, biological or clinical laboratory science. 3. During an interview on 11/15/2019 at 10:41 am, TP-4 and TP-5 confirmed the above findings.