Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2118967	11/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
Texas Surgical Dermatology Pa	21009 Kuykendahl Road Suite A, Spring, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
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 policy, laboratory records from 2019-2020, and confirmed in interview, the laboratory failed to document twice annual accuracy assessment for 1 of 2 tests (MOHS) in 2019. Findings were: 1. Review of the laboratory policy Quality Assurance Program - Mohs Histopathology revealed "once every 6 months, a quality assurance review of 10 Mohs cases will be performed. Ten past Mohs cases will be randomly selected by the laboratory's histotechnicians... results will be documented in the Quality Assurance section of the laboratory manual." 2. Review of the laboratory records from 2019-2020 revealed no documentation of the twice annual accuracy assessment for Mohs in 2019. 3. Random review of patient records from January to December 2019 revealed the laboratory performed 21 Mohs patient testing. 4/1/19 - Mohs Case #110, 111, 112 4/4/19 - Mohs Case #117, 118, 119, 120, 121 10/14/19 - Mohs Case #388, 389, 390, 391, 392, 393 10 /17/19 - Mohs Case # 394, 395, 396 10/21/19 - Mohs Case # 397, 398, 399, 400 4. An interview with the histotechnician on 11/13/20 at 1420 hours in the laboratory 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 observations, review of laboratory records, and confirmed in interview, the laboratory failed to ensure expired reagent for 1 of 2 testing (KOH - potassium hydroxide) were not used for patient testing. Findings were: 1. Surveyor observation on 11/13/20 at 1310 hours revealed the following expired reagents in the laboratory cabinet: KOH lot 1721311, exp 8/1/18 2. Review of the laboratory patient test log sheet from 2019-2020 revealed documentation that the laboratory performed 4 KOH patient testing using the above expired reagents. Refer to patient alias list. 3. An interview with the histotechnician on 11/13/20 at 1420 hours in the laboratory confirmed the above findings. She confirmed that that was the only KOH bottle in the laboratory and agreed it should be discarded.
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 the manufacturer's instructions, laboratory maintenance records from 2019-2020, patient test records, and confirmed in interview, the laboratory failed to document required maintenance for the Thermo Scientific Microtome Cryostat for 2019 and 2020. Findings were: 1. Review of the Thermo Scientific Microtome Cryostat instruction manual under Maintenance and care of the cryostat revealed "cleaning, care and decontamination of the cryostat depends on how frequently the instrument is used. However, it is recommended to shut the instrument off every 6-8 weeks." 2. Review of the laboratory records Cryostat Temperature from 2019-2020 revealed the following maintenance: - defrost of machine is done day of surgery - interior is clean day of surgery while wearing gloves -air filter is cleaned as part of the maintenance every month 3. Review of the laboratory records from 2019-2020 revealed no documentation of the above maintenance for the Thermo Scientific Microtome Cryostat for 2 of 2 years. 4. An interview with the histotechnician on 11/13 /20 at 1405 hours in the laboratory confirmed the above findings. She was unaware of the maintenance for the cryostat. She also stated that she does clean the cryostat each day of patient testing but she did not document it.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each

	special stain must be documented. (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 quality control records from 2019 -2020, patient test records, and confirmed in interview, the laboratory failed to document the slide quality of the Hemotoxin and Eosin (H & E) differential stain for 3 of 20 days of patient testing reviewed. Findings were: 1. A review of the quality control log for the H & E stain from January 2019 to October 2020 reveal no documentation of the slide quality for the H & E stain for 3 of 20 days reviewed. 10/14/19 10/17/19 10/21/19 2. Random review of patient test records for the above dates revealed the laboratory performed Mohs testing. 10/14/19 - Mohs Case #388, 389, 390, 391, 392, 393 10/17/19 - Mohs Case # 394, 395, 396 10/21/19 - Mohs Case # 397, 398, 399, 400 3. An interview of the histotechnician on 11/13/20 at 1430 hours in the laboratory confirmed the above findings.
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 review of the laboratory policy, quality control and patient records from 2019-2020, and confirmed in interview, the laboratory failed to document corrective actions when slide quality of the Hematoxin and Eosin (H & E) stain was unacceptable for 7 of 35 days reviewed. Findings were: 1. Review of the laboratory policy Histopathology Procedure Manual - Mohs Surgery under quality control revealed no documentation of the acceptable quality control criteria for stain quality of the H&E stain. 2. Review of the laboratory policy Histopathology Procedure Manual - Mohs Surgery under remedial actions revealed "all out of control situations not resolved by a simple repeat analysis will be reviewed by lab director as soon as practical after the event. The lab director will review the corrective actions to assume the appropriate action was taken and proper procedure followed. A corrective action form will be filled out whenever a problem arises in calibration or an out of control situation is not resolved by simple repeat analysis. 3. Random review of the quality control for for H&E stain quality from 2020 revealed 7 of 35 days with unacceptable H&E slide and no documentation of the corrective action prior to staining patient slides. 2/20/20 - [upward arrow] hem 4/1/20 - [upward arrow] eosin 4/13/20 - [upward arrow] hem 6/4/20 - [upward arrow] hem 6/18/20 - more blue 8/31/20 - [upward arrow] blue 9/14/20 - [upward arrow] blue (too pink) 4. Review of the patient test records from the above dates revealed the laboratory performed patient testing using the H&E stain. 2/20/20 - Mohs # 66, 67, 68 4/1/20 - Mohs # 116, 117 4/13/20 - Mohs # 124, 125 6/4/20 - Mohs # 176, 177, 179 6/18/20 - Mohs # 197, 198, 199, 200 8/31

	/20 - Mohs #310, 311, 312, 314 9/14/20 - Mohs # 324, 325, 326 5. An interview with the histotechnician on 11/13/20 at 1430 hours in the laboratory confirmed the above findings. She stated that the pathologist's notes on the above dates reviewed didn't indicate unacceptable stain, but she agreed that the lab policy doesn't include the acceptance criteria and that corrective actions should be documented if the stain quality is not 'Good'.