Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2049876	03/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
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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
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 procedures manual; Laboratory Personnel Report (FORM CMS 209); proficiency test records; and interview with the Histotechnician, the laboratory failed to verify the accuracy of its histopathology test procedures at least twice annually. Findings: 1. Laboratory procedures state that slides from each pathologist will sent to an independent laboratory twice a year. 2. There are 5 testing personnel listed on FORM CMS 209. One of them being the laboratory director. 3. Proficiency testing records show that 2 of 5 testing personnel performed twice yearly verification in 2018, 2019, and 2020. 4. On March 16, 2020 at 11:00 AM, in an interview with the surveyor, the histotechnician told the surveyor that the 2 pathologist read slides, and occasionally the laboratory director will render a second opinion of the diagnosis of the slide. 5. There was no documentation to show that the laboratory director performed twice yearly verication in 2018, 2013, and 2020. 6. On March 16, 2020 at 11:15 AM, the histotechnician confirmed the surveyor's findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual; patient testing logs; patient's test report, and interview with the histotechnician, the laboratory failed to establish and follow written policies and procedures for Specimen referral. Findings: 1. In a section titled, "Specimen Submission, Handling and Referral", it states, "No Specimens are referred out to any other laboratories. No specimens are accepted from any practice or laboratory outside the Fine Skin Dermatology practices." 2. Six patients' test records were selected from the patient testing logs. Documentation on 1 of 6 patients selected from the testing log shows that both the patient's slide and block were sent to a laboratory in Ohio for diagnosis. 3. Review of the 6 corresponding test reports from the 6 selected patients' test records revealed that the results (diagnosis) were reported by the laboratory in Ohio. 4. On March 16, 2020 at 12:00 PM, the histotechnician confirmed the surveyor's findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of manufacturer's procedures; laboratory policies and procedures manual; and maintenance records, and interview with the histotechnician, the laboratory failed to perform and document the maintenance activities of its Leica fume filter as specified. Findings: 1. There were no maintenance instructions supplied by the manufacturer of the laboratory's fume filter. 2. The laboratory's procedures reads as follows: "The fume filter must be changed at intervals not to exceed every 6-12 months if used on a daily basis. Longer intervals are acceptable if the strainer is utilized less frequently." 3. There was no procedure to show that the laboratory established exactly when and how often the fume filter is changed. 4. Review of maintenance records show that the "fume filter" was only changed on the following dates: a. January 15, 2018 b. November 1, 2019 5. On March 16, 2020 at 12:00 PM, the histotechnician confirmed the surveyor's findings.
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 the laboratory's procedures manual and quality control (QC) records and interview with the histotechnician, the laboratory failed to document all control procedures for its Hematoxylin and Eosin Stain performed, as specified. Findings: 1. The procedure for quality control reads as follows: "Each day specimens are stained; one patient specimen for each pathologist's batch of slides is cut in duplicate and stained with Hematoxylin and Eosin." 2. QC documentation shows that the laboratory only documented the range of slide numbers stained for the day. 3. There was no documentation to show which patient's specimens (slide) were used as the control for the day. 4. On March 16, 2020 at 12:00 PM, the histotechnician confirmed the surveyor's findings.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures; personnel records; quality control records; and maintenance records, and interview with the histotechnician, the laboratory did not have a general supervisor who provided general supervision in accordance with 493.1463 of this subpart. Findings: 1. The general supervisor did not provided day to day supervision of personnel performing high complexity testing. See D 6146 2. The general supervisor did not ensure that acceptable levels of analytic performance are maintained. See D6148 3. The general supervisor did not evaluate the performance of all testing personnel. See D6151
D6146	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(a)(2) The general supervisor is responsible for providing day-to-day supervision of high complexity test performance by a testing personnel qualified under 493.1489. This STANDARD is not met as evidenced by: Based on observation and interview, the general supervisor failed to provide day to day supervision of histopathology performance by testing personnel who performed the staining and gross examination of patients' tissue specimens. Findings: 1. During the date of survey (March 16, 2020), the only personnel performing testing were 2 persons who performed the staining of tissue specimens. One of the 2 persons performing the staining, also, performed the gross examination of patients' tissue specimens. 2. In an interview with the histotechnician, it was revealed that the general supervisor is not present when the processing tech and the histotechnician performs the cutting, staining and gross examination of patients' specimens. 3. On March 16, 2020 at 12:00 PM, the histotechnician confirmed the surveyor's findings.
D6148	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(a)(4) The general supervisor is responsible for monitoring test analyses and specimen

	examinations to ensure that acceptable levels of analytic performance are maintained. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and laboratory records and interview with the histotechnician, the general supervisor failed to be responsible for monitoring test analysis and specimen examination to ensure that acceptable levels of analytic performance are maintained. Findings: 1. The laboratory did not establish a maintenance procedure for it fume filter. Fume Filter Records show that testing personnel did not follow a schedule for changing the laboratory fume filter. 2. In the procedures manual, in section titled, "Limitations in test reliability," it states, "The use of too much heat in the water bath can distort the tissue causing parched earth effect..... Sections that exhibit this artifact are unacceptable and should be recut utilizing the manufacturers' recommended range." 3. Review of temperature charts for the water bath revealed that the laboratory did not record the actual measured temperature of the water bath from December 2019 through February 2020 for a total of 14 days in December 2019; 20 days in January 2020; and 21 days in February 2020. 4. Procedures of Quality Control of Hematoxylin and Eosin stain instruct the laboratory to cut one patient specimen from each pathologist's batch of slides as the Quality Control slide. There are also instructions to follow when the stain results do not demonstrate the tissue elements desired. 5. There is no general supervisor present to resolve staining issues during the day patients specimens are cut and stained. 6. There was no documentation to show the laboratory documented which slide was used as the control. 7. On March 16, 2020 at 12:00 PM, the histotechnician confirmed the surveyor's findings.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel. This STANDARD is not met as evidenced by: Based on review of Laboratory Personnel Report (FORM CMS 209) and personnel records and interview, the general supervisor failed to be responsible for evaluating and documenting the performance of all testing personnel who perform histology test. Findings: 1. There were a total of 5 testing personnel listed on FORM CMS 209. One of them being the laboratory director. 2. Review of personnel records revealed that there was no documentation to show the performance of 2 of 4 testing personnel was evaluated in 2018, 2019, and 2020. 3. On March 16, 202 at 12:00 PM, the histotechnician confirmed the surveyor's findings.