Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2120176	12/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Spring Hill Dermatology, Plc	1229 Reserve Blvd Suite 102, Spring Hill, TN	

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
D5201	CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231 The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with the histotech, the laboratory failed to ensure procedures were in place to protect patient confidentiality in 2022. The findings include: 1. Review of the laboratory's procedure manual revealed no policy that addressed protection of confidential patient information. 2. Interview on 12/9/22 at 1pm with the histotech confirmed the laboratory did not have policies and procedures to ensure patient confidentiality.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, lack of records, and an interview with the histotech, the laboratory failed to follow their quality assesment procedure in 2020, 2021 and 2022 for monitoring of patient testing throughout the testing process. The findings include: 1. Review of the laboratory's quality assessment plan revealed the laboratory would monitor each phase of the testing process to ensure accurate and reliable test results. 2. There was a lack of records documenting patient

	test managment reviews that included all phases of the testing process. 3. Interview on 12/9/22 at 1 pm with the histotech confirmed there was no quality assessment review of patient records from time of collection to final patient test report in 2020, 2021, and 2022.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with the histotech, the laboratory failed to ensure procedures were in place to document and investigate complaints against the laboratory. The findings include: 1. Review of the laboratory's procedure manual revealed no policy/procedure for documenting and investigating complaints. 2. Interview on 12/9/22 at 1pm with the histotech confirmed there was not a policy in place that addressed the procedures to follow in the event of a complaint against the laboratory.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with the histotech, the laboratory failed to ensure procedures were in place to assess personnel competency. The findings include: 1. Review of the laboratory's procedure manual revealed there were no personnel competency assessment policies or procedures. 2. Interview on 12/9/22 at 1 pm with the histotech confirmed the laboratory did not have written procedures for assessing personnel competency.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, review of the laboratory's quality assessment records, and interview with the histotech, the laboratory failed to follow their quality assessment policy in 2020, 2021 and 2022. The findings include: 1. Review of the laboratory's quality assessment plan revealed the following: a) The laboratory would perform ongoing monitoring of the total testing process to ensure

	accurate and reliable test results. b) The laboratory's quality assessment plan stated that a control slide would be evaluated each day and deemed acceptable by the MOHS surgeon. c) Reciprocal reading of slides between MOHS surgeons or other pathologist would occur using a minimum of two random cases twice per year. 2. Review of the laboratory's records revealed the following: a) There were no retrospective quality assessment reviews from December 2020 to the date of the survey on 12/9/22. b) There was no documentation that the MOHS surgeon had evaluated the daily Hematoxylin and Eosin (H&E) quality control slides for five of five months reviewed (December 2020, April 2021, August 2021, February 2022, November 2022). c) The laboratory's MOHS Frozen Section Quality Assurance reciprocal reading forms revealed the laboratory did not perform reviews twice per year in 2020 and 2022. 3. Interview on 12/09/2022 at 1pm with the histotech confirmed the laboratory failed to follow it's own quality assessment plan when it did not perform quality assessment reviews, the MOHS surgeon did not document the acceptability of the daily H&E quality control slides, and did not ensure reciprocal reading of MOHS cases for accuracy twice per year as indicated in the plan.
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 observation of the laboratory, review of manufacturers' instructions for use, lack of records, and interview with the histotech, the laboratory failed to monitor room temperature and humidity in the area where the cryostat and autostainer were being used for processing and staining of tissue removed during MOHS procedures. Finding include: 1. Observation of the laboratory on 12/9/22 at 8 am revealed equipment in use for performing processing and H&E staining of tissues removed during MOHS procedures. The equipment included a cryostat and automated stainer. No devices for monitoring temperature or humidity were noted in the laboratory. 2. Review of the cryostat and autostainer instructions for use revealed the following environmental operating conditions: Leica cryostat - operating temperature of +18 degrees Celsius to +35 degrees Celsius, operating relative humidity of 20% to 60%. HistoPro 414 automated stainer- operating temperature of 15 degrees Celsius to 30 degrees Celsius, operating relative humidity of 20% to 80%. 3. There was a lack of records for monitoring of room temperature and humidity. 4. Interview on 12/9/22 at 1 pm with the histotech confirmed the laboratory did not have a process in place to monitor room temperature or humidity in the area where the cryostat and autostainer were located.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate

	training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), lack of records, and interview with histotech, the laboratory director failed to ensure testing person number two had been evaluated and demonstrated accuracy prior to performing interpretation of histopathology slides on tissue removed during MOHS surgical procedures. The first patient was tested on 07/11/22 with approximately 292 MOHS cases done since testing person number two began on 07/11/22 until the date of the survey on 12/09/22. The findings include: 1. Review of the Form CMS-209 revealed testing person number two listed as a high complexity testing person. 2. There were no records where the lab director had evaluated the competency of testing person number two. 3. Review of MOHS surgical case logs and surgical reports revealed the second provider began performing testing personnel duties to include reading of H&E histopathology slides starting on 07/11/22 (patient number 102714). 4. Interview on 12/09/22 at 1pm with the histotech confirmed the laboratory director failed to assess the accuracy of testing person number two prior to performing patient testing in 2022. 5. Email communication on 12/14/22 at 3:47 pm revealed testing person number two had performed histopathology testing procedures on 292 patients since beginning testing on 07/11/22.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the Form CMS-209, review of laboratory records, and interview with histotech, the laboratory director failed to ensure a written job description and delegations in writing for the second provider performing clinical consultant and testing personnel duties in performance of histopathology procedures on tissue removed during MOHS surgical procedure. The findings include: 1. Review of the Form CMS-209 revealed a second clinical consultant and testing person other than the laboratory director. 2. Review of laboratory records revealed no job description or delegations in writing by the laboratory director for the second provider who was listed on the Form CMS-209 as performing clinical consultant and testing personnel duties. 3. Review of MOHS surgical case reports revealed the second provider began performing clinical consultant and testing personnel duties starting on 07/11/22 (patient number 102714). 3. Interview on 12/09/22 at 1pm with the histotech confirmed the laboratory director failed to delegate in writing the clinical consultant and testing personnel duties for provider number two.