

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D1088945	<b>(X3) Date Survey Completed</b> 06/26/2023
<b>Name of Provider or Supplier</b> Spring Dermatology	<b>Street Address, City, State</b> 20311 Kukendahl Rd, Spring, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was found out of compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found in compliance with applicable CLIA conditions, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's submitted form CMS 209, review of personnel records and staff interview, the laboratory failed to document competency assessment for technical supervisor and general supervisor positions for two of three personnel. Findings included: 1. Review of laboratory's submitted form CMS 209 (signed by laboratory director on 06/26/2023) revealed the laboratory employed three personnel with the titles of technical supervisor and general supervisor. 2. Review of personnel records revealed two of three personnel holding the titles of both technical supervisor and general supervisor did not have documentation of competency assessment for</p>

those roles. These were: Technical Supervisor number 2 / General Supervisor number 2 Technical Supervisor number 3 / General Supervisor number 3 3. In an interview on 06/26/2023 at 1430 hours in the office, the laboratory's Technical Supervisor number two (as indicated on submitted form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid

**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 laboratory's twice annual test accuracy verification records, laboratory's policies/procedures and staff interview, the laboratory failed to document twice annual Mohs accuracy verification for 2 of 2 events in 2022. Findings included: 1. Review of laboratory's twice annual Mohs accuracy verification documents for 2021, 2022 and 2023 revealed the laboratory documented test accuracy verification as follows: 04/01/2021 09/10/2021 11/05/2021 May 2023 There was no documentation for twice annual test accuracy verification for 2022. 2. Review of the laboratory's "Mohs Laboratory Procedure Manual Histopathology Mohs Surgery" (last reviewed 10/20/2020) revealed: "PROFICIENCY TESTING ... Random selection of Mohs surgical cases are chosen every six months." 3. In an interview on 06/26/2023 at 1600 hours in the office, the laboratory's Technical Supervisor number two (as indicated on submitted form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid

**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 laboratory's microscope maintenance records, quality control records for Hematoxilin and Eosin (H&E) histopathology stain and staff interview, the laboratory failed to document microscope maintenance for 38 of 38 days the microscope was in use as per laboratory requirements. Findings included: 1. Review of laboratory's microscope maintenance records revealed: "Microscope Maintenance ... 1. Microscope stage and ocular pieces are to be cleaned daily." 2. Review of quality control records for Hematoxilin and Eosin (H&E) histopathology stain and corresponding days' microscope maintenance records from February to June 2023 revealed microscope maintenance was not documented for the following 38 of 38 days H&E stain was performed and interpreted using the microscope: Date: 02/08/2023 02/15/2023 02/17/2023 02/21/2023 02/23/2023 02/28/2023 03/01/2023 03/03/2023 03/08/2023 03/10/2023 03/15/2023 03/21/2023 03/23/2023 03/28/2023 03/30/2023 04/04/2023 04/06/2023 04/11/2023 04/13/2023 04/18/2023 04/20/2023 04/25/2023 04/27/2023 05/02/2023 05/04/2023 05/09/2023 05/11/2023 05/16/2023 05/18/2023 05/23/2023 05/25/2023 05/30/2023 06/01/2023 06/06/2023 06/09/2023 06/13/2023 06/16/2023 06/22/2023 3. In an interview on 06/26/2023 at 1510 hours in the

office, the laboratory's Technical Supervisor number two (as indicated on submitted form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid

**D6143**

**GENERAL SUPERVISOR QUALIFICATIONS**

CFR(s): 493.1461

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) 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; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493.1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual

who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:

A. Based on review of laboratory's submitted form CMS 209, personnel records and staff interview, the laboratory failed to document identification of personnel delegated to perform grossing for 1 of 3 testing personnel employed by the facility. Findings included: 1. Review of laboratory's submitted form CMS 209 revealed the laboratory employed three testing personnel. 2. Review of personnel records revealed Testing Person number three (as indicated on submitted form CMS 209) started testing in February 2023. Personnel records for Testing Person number three did not have delegation of grossing of histopathology samples. 3. In an interview on 06/26/2023 at 1445 hours in the office, the laboratory's Technical Supervisor number two (as indicated on submitted form CMS 209) confirmed the findings. B. Based on review of the laboratory's grossing records, histopathology case records and staff interview, the laboratory failed to ensure physical examinations/measurements/markings /inking /descriptions of tissue (grossing) performed in the absence of the technical supervisor by qualified individuals from February to June 2023 were reviewed within 24 hours by a technical supervisor for 973 of 973 cases diagnosed within the interval. Findings included: 1. Review of the laboratory's random grossing records from February to June 2023 revealed grossing of histopathology samples was performed by Testing Person number three. There was no documentation of grossing descriptions' review by a technical supervisor within 24 hours of grossing completion. 2. Review of histopathology case records from February to June 2023 revealed 973 cases were diagnosed during the interval. 3. In an interview on 06/26/2023 at 1450 hours in the office, the laboratory's Technical Supervisor number two (TS2) confirmed that grossing of all 973 histopathology cases was performed by Testing Person number three, and she (TS2) did not document her review of grossing within 24 hours of grossing completion. Key: CMS - Centers for Medicare and Medicaid