

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D0935037	<b>(X3) Date Survey Completed</b>  07/17/2023
<b>Name of Provider or Supplier</b>  Dermatology Center/ Vital Skin Derm	<b>Street Address, City, State</b>  2857 Charlestown Road, Ste 100, New Albany, IN	
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>	A recertification survey was completed on 7/17/2023. It was determined that the following condition-level deficiencies existed: 42 Code of Federal Regulation (CFR) 493.1487 Testing Personnel
<b>D3043</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to retain paraffin blocks/cassettes for at least 2 years from the date of examination for three out of thirteen patient test samples reviewed (PT#7 thru PT#9) of microscopic examinations completed from January 19, 2022, through November 28, 2022. Findings Include: 1. On 7/17/23 at 12:35 pm, SP-1(testing person) and SP-2 (site manager) acknowledged they did not have cassettes for the paraffin microscopic examinations performed in 2022. 2. Review of a document no title and not date read, "As of November 28, 2022, paraffin (sic) is no longer performed in this laboratory." 3. Review of microscopic examination slides for patient records (PT-7 thru PT-9) revealed 1 cassette was created for each patient specimen. 4. Per patient record request the following patients did not have the paraffin cassettes retained: Patient (PT) TEST DATE TEST TYPE PT#7 1/19/22 Microscopic PT#8 6/30/22 Microscopic PT#9 11/18/22 Microscopic 5. Annual Test Volume for histopathology is approximately 720.</p>
<b>D5209</b>	<b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b>

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 document review and interview, the laboratory failed to follow a Personnel Competency Assessment policy for three of three (SP-1, SP-3, and SP-5) testing person(s) performing grossing, cutting, and inking of frozen tissue specimens were competent in the duties of a histotechnologist were qualified. Finding(s) include: 1. Review of the "Laboratory Personnel Report (CLIA) form CMS 209", signed by the laboratory director on 7/10/2023, indicated the following: a. SP-1 is a high complexity testing person. b. SP-3 is a high complexity testing person. c. SP-5 is high complexity testing person. 2. On 7/17/2023 at 10:05am, SP-1 confirmed SP-1, SP-3, and SP-5 perform grossing (cutting and inking for MOHs) and grossing for frozen specimens. 3. On 7/17/23 at 2:30 pm, upon request for competency documents for SP-1 (testing person), SP-3 (testing personnel), and SP-5 (testing person), SP-1 provided two blank forms for Personnel Assessment and employee evaluation forms. 3. Review of document titled, "Proficiency Testing: Competency and CLIA competency Assessment", not signed by the laboratory director states, "evaluation and documenting competency of personnel responsible for testing is required semiannually, ...competency assessment must be performed for testing personnel for each test and approved by the director, and results of each competency test will be entered in a log and kept ...as part of its permanent records." 4. Review of "Job descriptions for laboratories Performing Tests of High Complexity" for laboratory director responsibilities are to ...(11) Ensure that, prior to testing specimens, all personnel have appropriate education, receive the appropriate training for the type of complexity, (12) monitor individuals who conduct testing to assure they are competent and maintain competency to process specimens (14) specify, in writing, the responsibilities and duties of each consultant person engaged in testing, Section IV- page 14, October 1993. 5. Review of "Part 1: Quality Assessment Procedures", signed by the laboratory director on 7/24/17, under Ongoing Assessment states, "The competency for Testing Personnel and all staff members will be evaluated and documented every year. 6. Annual Test Volume for histopathology is approximately 720.

**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 document review, the laboratory failed to document the maintenance activities for three of nine patient's specimens (PT-5, PT-7, and PT-8) prepared on a

Cryostat Avantik, QS12 on 12/07/22, 1/19/22, and 6/30/22. Finding(s) include: 1. Review of maintenance log titled, "2022 daily Routine Maintenance" revealed the following: a. No maintenance was performed on dates 12/07/22, 1/19/22, and 6/30/22 for the Cryostat Avantik, QS12. b. The following six of eight cleaning task(s) were not performed (tasks: 1,2,3,4,7 and 8) for those dates in 2022 as listed below: 1) Clean all laboratory equipment according to manufacturer recommendations. 2) Wipe down all countertops, cutting boards, top of cryostat and instruments with .05% bleach or similar disinfectant daily. 3) Cryostat will be wiped out with dry gauze to gather excess scrapings, then cleaned appropriately with alcohol 4) Manual Defrost will be run at end of each workday 5) Staining set up will be changed as needed 6) Temperature charts and logs are checked daily or when lab in use 7) Document that daily maintenance has been completed by initialing daily maintenance log 8) Changes and updates documents as needed 2. Review of patient records (PT-5, PT-7, and PT-8) indicated the following patients' slides were created when maintenance activities were not documented: Patient (PT) TEST DATE TEST TYPE PT#5 12/07/22 MOHs PT#7 1/19/22 Microscopic PT#8 6/30/22 Microscopic 3. Review of "Mohs Technician job description" indicated the responsibilities of the Mohs technician is to ... (1) check daily operation, checks temperature, all equipment, machines, and documents (6) perform daily cleaning of the laboratory and (7) perform weekly maintenance on the cryostat microtome. 4. Annual Test Volume for histopathology is approximately 720.

**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 record review and interview, the laboratory failed to create and document review of quality control (QC) slides for known reactivity for nine out of thirteen patient test samples reviewed (PT#1 through PT#9) of Micrographically Oriented Histographic Surgery (MOHs) Slides and microscopic examinations completed from July 21st, 2022, through January 5th, 2023. Findings Include: 1. On 7/17/23 at 12:35pm, SP-1 (testing person) and SP-2 (site manager) acknowledged Quality Control (QC) slides were not created or reviewed from July 21, 2022, to January 5th, 2023. 2. Review of a document titled, "The Dermatology Center", no date of creation, acknowledged that no QC slides were created for patient test samples from July 21st, 2022, through January 5th, 2023. 3. Review of Micrographically Oriented Histographic Surgery (MOHs) Slides and microscopic examination slides for patient records (PT-1 thru PT-9) revealed no quality control (QC) slides were reviewed or created on patients prior to January 5th, 2023. 4. The following patients did not have a review of a quality control (QC) slide. Patient (PT) TEST DATE TEST TYPE PT#1 7/21/22 MOHs PT#2 8/04/22 MOHs PT#3 10/11/22 MOHs PT#4 11/23/22 MOHs PT#5 12/07/22 MOHs PT#6 12/29/22 MOHs PT#7 1/19/22 Microscopic PT#8 6/30/22 Microscopic PT#9 11/18/22 Microscopic 5. Review of "Job descriptions for laboratories Performing Tests of High Complexity" states, laboratory director duties

...." Ensure that quality control and quality assurance programs are established and maintained...and to identify failures in quality that occur," Section IV-page 13, October 1993. 6. Annual Test Volume for histopathology is approximately 720.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to follow policies and procedures to monitor and assess quality control slides and logs from July 21st, 2022, through January 5th, 2023. Findings Include: 1. On 7/17/23 at 12:35 pm, SP-1 (testing person) and SP-2 (site manager) acknowledged Quality Control (QC) slides were not created or reviewed from July 21, 2022, to January 5th, 2023. 2. Review of a document titled, "The Dermatology Center", no creation date, acknowledged that no QC slides were created for patient test samples from July 21st, 2022, through January 5th, 2023. 3. Review of "Job descriptions for laboratories Performing Tests of High Complexity" states, laboratory director duties ...." Ensure that quality control and quality assurance programs are established and maintained...and to identify failures in quality that occur," Section IV-page 13, October 1993. 4. Review of "Part 1: Quality Assessment Procedures", reviewed by laboratory director on 7/24/17, under Ongoing Assessment states, "All Quality Control (QC) records log sheets will be reviewed by the laboratory director" or designated staff member quarterly. 5. Review of four quarterly "Quality Assurance Meeting" documents, signed by the laboratory director on 4/11/22 (1st quarter), 8/12/22 (2nd quarter), 10/16/22 (3rd quarter), and 1/16/23 (4th quarter) for QA meetings indicated, "All QA Sections were met ...no problems, no changes, and lab operating normally". 6. Annual Test Volume for histopathology is approximately 720.

**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 document review and interview, the laboratory failed to specify, in writing, the responsibilities and duties for one of three testing persons) (SP-1) listed on the CMS 209 form as personnel involved in high complexity testing. Finding(s) include: 1. On 7/17/23 at 10:35am, upon request for a job description for SP-1 (testing person), SP-1 was not able to provide documentation to confirm the duties/ responsibilities for testing person performing high complexity testing. SP-1 was then asked to explain

their duties/responsibilities, per SP-1, duties involved grossing, inking, and preparation of frozen specimen samples, and "all the job duties" performed by SP-5 (testing person). 2. Review of "Laboratory Personnel Report (CLIA) form CMS 209", signed by laboratory director on July 10, 2023, identified SP-1 as a testing person for high complexity testing. 3. Annual Test Volume for histopathology is approximately 720.

**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 document review and interview, the laboratory failed to ensure two of three testing person(s) (SP-1 and SP-3) performing high complexity testing for histopathology was qualified from 10/17/2022 to the date of the survey (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 document review and interview, the laboratory failed to ensure two of four testing person(s) performing high complexity testing (SP-1 and SP-3) qualified as a high complexity testing person from 10/17/2022 to the date of the survey. Finding(s) include: 1. Review of the "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the laboratory director on 7/10/23, indicated the following: a. SP-1 was a testing person. b. SP-3 was a testing person. 2. On 7/17/23 at 10:05 am, upon request for education documentation for SP-1 (testing person), SP-1 provided a high school diploma and a training certificate titled "Mohs Micrographic." Upon request for a higher level of education other than a High School diploma, SP-1 confirmed there was no other education completed. 3. On 7/17/23 at 10:15 am, SP-1 explained they had a change in position for SP-1 from a clerical person to a testing person, effective on 10/17/22 after SP-5 (testing person) was transferred to another site. 4. On 7/17/23 at 10:35 am, upon request for job description for SP-1 (testing person) and SP-3 (testing person), SP-1 was not able to provide documentation to confirm the duties/responsibilities for Testing person(s) for high complexity testing. SP-1 was then asked to explain their duties/responsibilities, per SP-1, it involved grossing, inking, and preparation of frozen specimen samples, and "all the job duties" performed by SP-5 (testing person). 5. Review of transcripts from Kennesaw State College (Major: Psychology and Minor: Biology) provided for SP-3 (testing person) indicated a total of 6.9 credit hours towards science and medical laboratory courses that did not meet the requirements for high complexity testing (inking, mapping, and grossing). 7. Annual Test Volume for histopathology is approximately 720.