Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D1014635	07/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Skin Care Drs Pa	1350 Lesauk Drive, Sartell, MN	

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	The Skin Care Doctors, PA laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on July 10, 2024. The following condition-level deficiency was cited: 493.1487 Laboratories performing high complexity testing: testing personnel The following standard-level deficiencies were cited: 493.1451 Technical supervisor responsibilities 493.1489 Testing personnel qualifications .
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Technical Supervisor failed to ensure an initial competency assessment was competed for one of one testing personnel in 2024. Findings are as follows: 1. The laboratory performed Mohs Micrographic surgery under the subspecialty of Histopathology as confirmed by the Practice Administrator (PA) during a tour of the laboratory at 1:05 p.m. on 07/10 /24. Mohs Micrographic surgery was suspended September 2022 through December 2023 and reinstated on 01/24/24. 2. Testing Personnel 1 (TP1) performed the high complexity tissue inking component as confirmed by TP1. 3. TP1 obtained a Mohs training certificate in January 2023. Documentation provided on 07/17/24 indicated TP1 did not possess the required education to perform high complexity testing. See D6171. 4. A tissue inking competency assessment procedure was not found in the

	Mohs Policy and Procedure Binder. The laboratory was unable to provide the missing procedure upon request. 5. Initial competency assessment documentation for tissue inking was not found for TP1. The laboratory was unable to provide the missing record upon request. 6. In an interview at 1:00 p.m. on 07/10/24, the PA confirmed the above finding. .
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 review of education documents and interview and email communication with laboratory personnel, the laboratory failed to ensure personnel performing high complexity testing meet the qualification requirements of 493.1489. Findings are as follows: The laboratory failed to ensure one of one Histopathology testing personnel met the qualification criteria to perform high complexity testing. See 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 and email communication with laboratory personnel, the laboratory failed to ensure one of one Histopathology tissue processing personnel met the qualification criteria required to perform high complexity testing in 2024. Findings are as follows: 1. The laboratory performed Mohs Micrographic surgery under the subspecialty of Histopathology as confirmed by the Practice Administrator (PA) during a tour of the laboratory at 1:05 p.m. on 07/10/24. Mohs Micrographic surgery was suspended September 2022 through December 2023 and reinstated on 01/24/24. 2. Testing Personnel 1 (TP1) performed the high complexity tissue inking components confirmed by TP1. 3. TP1 obtained a Mohs training certificate in January 2023. Additional education credentials were not available on date of survey. The laboratory was given five days to provide TP1's education credentials. 4. In an interview at 1:00 p.m. on 07/10/24, the PA confirmed the above finding. 5. In an email received at 9:12 a.m. on 07/17/24, the PA provided TP1's Medical Assistant Associate of Applied Science Degree. This degree did not include the required education to perform high complexity testing. 6. In an email received at 10:11 am on 07/17/24, the PA acknowledged this finding. .