Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2016521	08/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Skin Care Center, The	2551 Compass Rd, Ste 105, Glenview, IL	

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
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, review of the Laboratory Personnel Report (CMS 209), manual, and an interview with the testing personnel (TP), the laboratory failed to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized, affecting 5 out of 5 TP, Findings: 1. On 08/21 /2018 at 11:30 AM during a tour of the laboratory, the surveyor observed the following: a). Massive amounts of paraffin covering the histology bench and wall next to the tissue embedding instrument; b). Massive amounts of paraffin waste caked on the lid of the garbage can placed under the tissue embedding machine. c). No biohazard warning labels on the tissue embedding machine, microtome, microwave, staining station, or cryostat machine. 2. The CMS 209 list 5 employees testing in the laboratory. 3. The laboratory manual does not include cleaning and sanitizing procedures for all equipment, specimens, instruments, reagents, materials, and supplies used for processing of human tissue. 4. On a Recertification survey conducted on 08/21/2018 at 3:00 PM, the TP confirmed the above findings.
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 the surveyor's review of the Laboratory Personnel Report (CMS 209), the laboratory's policies, procedures and records, and an interview with the testing personnel (TP); the laboratory failed to establish written policies and procedures that meet the personnel requirements in subpart M to assess employees performing Bacteriology testing, affecting 2 out of 2 testing personnel (TP). Findings: 1. The CMS 209 lists on lines 4 and 5; 2 licensed physicians (TP-1A and TP-2B) performing Potassium Oxide (KOH) and Scabies testing in the laboratory. 2. The personnel documents reveal that the 2 TP have not been trained or assess as competent to perform KOH and Scabies testing, prior to testing patients. 3. The laboratory's manual does not include an established competency policy and step-by-step procedure for the TP performing KOH and Scabies testing which includes the following: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; b). Monitoring the recording and reporting of test results (for example, recording patients and their results in the labs' test log and/or EMR system); c). If applicable, review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; d). Direct observation of performance of instrument maintenance and function checks (i.e. microscope maintenance, etc.); e). Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and f). Assessment of problem solving skills; and g). Evaluating and documenting the performance of individuals responsible for moderately complex testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually. 4. On a Recertification survey conducted on 08/21/2018 at 2:15 PM, the TP confirmed the above findings.
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 the surveyor's review of the laboratory's policies, procedures, test records, and an interview with the testing personnel (TP); the laboratory failed to verify the accuracy of tests performed in the specialty of Microbiology and procedures and tests performed in the specialty of Histopathology at least twice annually, for the years of 2016 through 2018. Findings: Bacteriology findings: 1. The manual and test records reveal that the laboratory performs the following tests: Potassium Hydroxide (KOH) preparations (Preps) and Scabies testing. 2. The laboratory's manual does not define the method and procedure the laboratory will use to verify the accuracy of its KOH and Scabies testing. 3. The laboratory was performing the tests listed in findings #2 during the years of 2016 through to the date of survey on 08/21/2018. Histopathology findings: 4. The laboratory manual established the following procedures to verify the accuracy of the Mohs surgery and Histopathology testing performed in the laboratory: a). Selected slides from the Mohs surgery procedure are to be submitted to the American Society for MOHS Surgery (ASMS) for "Peer Review" twice a year; and b). Selected Histology slides will be submitted to a Dermatopathologist (from a CLIA certified laboratory) twice a year to verify the accuracy of its Histopathology slide interpretations. 5. The ASMS documents presented revealed the following: Mohs

	Surgery: a). One case dated 10/05/2016 submitted for review during the year of 2017; b). One case dated 11/01/2017 submitted for review during the year of 2018; no other documented evidence was provided as proof the laboratory submitted other cases during the years of 2017 and 2018 to fulfill the twice annual verification requirements for their Mohs surgery testing. Histopathology Slide interpretations a). No documented evidence of case submissions for Histopathology interpretations review was presented for the years of 2016, 2017 and 2018. 6. The test records and logs show that TP-S3T (listed on line 1) read Histopathology slides during the years of 2016 through 2018. 7. On a Recertification survey conducted on 08/21/2018 at 3:00 PM, the TP confirmed the above findings.
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 the surveyor's review of the Laboratory Personnel Report (CMS 209), personnel files, records, and an interview with the testing personnel (TP); the laboratory director (LD) failed to 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, affecting 3 out of 4 TP. Findings: 1. The CMS 209 lists on lines 2 thru 5, four TP; two TP performing Potassium Oxide (KOH) and Scabies testing and two TP performing Histology tissue grossing and processing, in the laboratory. 2. The employee files and competency records reveal the following: a). TP-3AG (listed on line 3) file had no documentation of education credentials, training, or competency assessment to perform tissue grossing and processing, prior to testing patients. See D6168 and D6171. b). TP-E2 (listed on line 4) and TP-HZ (listed on line 5) files had no documented proof of training and competency assessment to perform KOH and scabies testing, prior to testing patients. 3. On a Recertification survey conducted on 08/21/2018 at 2:00 PM, the TP confirmed the above findings.
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 the surveyor's direct observation, review of the Laboratory Personnel Report (CMS-209), employee files, and an interview with the testing personnel (TP), the laboratory failed to employ individuals who meet the qualification requirements of

	493.1489 for testing personnel (TP). Finding: 1. The laboratory failed to ensure laboratory personnel meet the qualification requirements for performing highly complex testing in the Specialty of Histopathology. 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 the surveyor's direct observation, review of the Laboratory Personnel Report (CMS-209), employee files, and an interview with the testing personnel (TP), the laboratory failed to ensure laboratory employees meet the qualification requirements for testing personnel (TP) as defined in 493.1489. Findings: 1. On 08/21/2018 at 11: 30 AM during a tour of the laboratory, the surveyor observed TP-3AG (listed on line 3 of the CMS 209) performing tissue grossing (highly complex procedure) and processing at the Histology workstation. 2. The employee file of TP-3AG's does not include education credentials, proof training, and competency assessment to perform tissue grossing and processing, prior to testing patients 3. On a Recertification survey conducted on 08/21/2018 at 3:00 PM, the TP confirmed the above findings.