Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2045518	08/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Soma Skin & Laser	90 Millburn Ave, Millburn, NJ	

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
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor review of Quality Control records (QC), Procedure Manual (PM) observation of reagents and interview with the Office Manager (OM), the laboratory failed to ensure that quality systems for the pre-analytical, analytic and post-analytical phases of Histopathology testing were monitored from 12/12/18 to the date of survey. 1. The laboratory the laboratory failed to verify the accuracy and reliability of Moh's testing. Cross Refer to D5217. 2. The laboratory did not ensure Reagents were labeled with preparation and expiration dates. Cross Refer to D5415 3. The laboratory failed to perform and document annual maintenance. Cross refer to D5429 4. The laboratory did not document all control procedures performed. Cross Refer D5601 5. The laboratory the laboratory failed to ensure that the FR included the name and address of the laboratory where testing was performed. Cross Refer D5805
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 surveyor review of the Procedure Manual (PM), lack of Biannual Assessment (BA) records and interview with the Office manager (OM), the laboratory

	failed to verify the accuracy and reliability of Moh's testing twice a year in the calendar years 2021 and 2022. The finding includes: 1. No BA was perfomed in 2021 and in the first six months of 2022. 2. The OM confirmed on 8/18/22 at 11:00 am that the laboratory did not verify the accuracy of Moh's testing twice a year.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A) Based on surveyor review of the Procedure Manual (PM), and interview with the Office Manager (OM), the laboratory failed to follow all procedures written for Moh's tests from 10/16/20 to the date of the survey. The findings include: 1. There was no documented evidence the below mentioned procedures were followed: a. "Equipment Maintenance", "Equipment Quality Control - Microscope", "1. Microscope stage and ocular eye pieces are to be cleaned weekly." , "3. Routine preventive maintenance will be performed yearly". b. "Equipment Quality Control - Cryostat", "9. Preventive maintenance is performed yearly". c. "Mohs Surgery Procedure Manual", "Review Policy", "This procedure manual is reviewed by the laboratory director annually" 2. The OM confirmed on 8/18/22 at 10:30 am that the laboratory did not follow the PM. B) Based on surveyor review of the Procedure Manual (PM), and interview with the Office Manager (OM), the laboratory failed to have a staining procedure written for Moh's tests performed with Toluidin Blue reagent from 10/16/20 to the date of the survey. The OM confirmed on 8/18/22 at 10:30 am that the laboratory did not have the aforementioned written procedure. C) Based on surveyor review of the Procedure Manual (PM), observation of Staining Station (SS) and interview with the Office Manager (OM), the laboratory failed to follow the PM for Hematoxyilin-Eosin (HE) staining from 10/16/20 to the date of the survey. The findings include: 1. The SS in the laboratory did not correspond with the staining procedure in the PM. 2. The observation of the staining solutions and reagents in the SS were as follows: 95% alcohol, Hematoxylin, Scotts Blueing Reagent, 100% alcohol, Eosin, 100% alcohol, Tap Water, 1% Acid alcohol, Subxylene, 100% alcohol, Subxylene, 95% alcohol in staining stations one through twelve. 3. The PM stated Hemotoxylin, Tap water Rinse, Acid Alcohol, Tap water Rinse, Scotts Bluing solution, Tap water Rinse, 95% alcohol, Eosin, 95% alcohol, 100% alcohol, Subxylene for stations one through eleven. 4. The OM confirmed on 8/18/22 at 10:30 am that the laboratory did not follow the PM. D) Based on surveyor review of the Procedure Manual (PM), the lack of Biannual Assessment (BA) results and interview with the Office Manager (OM), the laboratory failed to follow the PM for "6. Quality Control" from 10/16/20 to the date of the survey. The findings include: 1. The PM stated "6.3.1 Twice annually, two cases will be randomly selected for proficiency testing by an independent pathologist" 2. There was no documented evidence that the aforementioned procedure was followed. 3. The OM confirmed on 8/18/22 at 10:30 am that the laboratory did not follow the PM.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of the Flammable Cabinet and interview with the Office Manager (OM), the laboratory failed to appropriately label Toluidine Blue reagent used for Histopathology testing from 10/16/20 to the date of the survey. The findings include: 1. Two storage containers were labeled incorrectly as follows: a. Both storage containers containing Toluidine Blue were labeled "10% Neutral Buffered Formalin specimen Transport Container". 2. There were no preparation and expiration dates on the aforementioned containers. 3. The OM confirmed on 8/18/22 at 10:35 am that all reagents were not labeled correctly.
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 lack of maintenance records and interview with the Office Manager (OM), the laboratory failed to perform and document annual maintenance on the microscope and Cryostat used in Moh's testing from 10/16/20 to the date of the survey. The OM confirmed on 8/18/22 at 10:35 am there was no documented evidence that annual maintenance was performed.
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 surveyor review of Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to document Hematoxylin and Eosin (H&E) and Toluidine Blue (TB) control slide reaction from 10/26/20 to the date of survey. The findings include: 1. The laboratory did not document H&E and TB stain QC reaction for reading of Moh's slides. 2. The laboratory read and reported 41 patient slides. 3. The OM confirmed on 8/18/22 at 10:40 am that the laboratory did not document H&E and TB QC stain reaction.
D5805	TEST REPORT

	CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Office Manager (OM) the laboratory failed to ensure that the FR included the name and address of the laboratory where testing was performed from 10/16/20 to the date of survey. The OM confirmed on 10/16/20 at 10:00 am that the FR did not have name and address of the laboratory where testing was performed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a interview with the Offide Manager (OM), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 10/16/20 to the date of the survey. 1. The LD failed to ensure BA was performed to evaluate the laboratory's performance accurately. Cross refer D6091 2. The LD failed to ensure that the laboratory maintained a QC program. Cross refer D6093 3. The LD failed to ensure that the education and training records were available. Cross refer D6102 4. The LD Failed to ensure Testing Personnel were qualified to perform Moh's Tissue processing. Cross refer D6171
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on the lack of the Biannual Assessment (BA) records and interview with the Office Manager (OM), the Laboratory Director failed to ensure BA was performed to evaluate the laboratory's performance accurately 10/16/20 to the date of survey. The TP confirmed on 7/23/21 at 1:00 pm the BA was not performed to evaluate the laboratory's performance accurately.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Office Manager (OM), the Laboratory Director failed to ensure that the laboratory maintained a QC program from 10/16/20 to the date of the survey. The findings include: 1. There was no documented evidence that Stain Quality was monitored. 2. There was no documented evidence of reagent changes. 3. There was no documented evidence that a control slide was observed on each day of patient testing. 4. There was no documented evidence that the Cryostat temperature was in range on 11/30/22. 5. The OM confirmed on 8/18/22 at 11:00 am the laboratory did not ensure a QC program was maintained.
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 lack of Personnel Records (PR) and interview with the Office Manager (OM), the Laboratory Director failed to ensure that the education and training records were available on the date of the survey. The finding includes: 1. Education and training records were not available for one out of one TP. 2. The OM confirmed on 8 /18/22 at 10:30 am that all education and training records were not available.
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 lack of Personnel Files and interview with the Office Manager (OM), the Laboratory Director (LD) failed to ensure Testing Personnel were qualified to perform Moh's Tissue processing from 10/16/20 to the date of survey. The OM confirmed on 8/18/22 at 10:50 am the LD failed to ensure Testing Personnel were qualified to perform Moh's Tissue processing.