Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0936621	07/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laser And Skin Surgery Center Of Indiana	8925 N Meridian Street, Ste 200, Indianapolis, IN	

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	48225 A recertification survey was completed on 7/11/2023. It was determined that the following condition-level deficiencies existed: 42 Code of Federal Regulation (CFR) 493.1487 Testing Personnel
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 record review, lack of documentation, and interview, the laboratory failed to establish and follow a written policy to assess employee and consultant competency for two (SP-1 and SP-2) of two personnel performing testing and consultant duties for the laboratory. Findings include: 1) Review of the "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the laboratory director on "7/10/23," indicated SP1 was the laboratory director, technical supervisor, clinical consultant, and testing person and SP2 was a testing person. 2) Review of policy and procedure manual indicated there was no policy for consultant or testing person competency. 3) Upon request for policy on consultant and testing person competency, on 7/11/23 at 1:37 pm, SP2 (Laboratory Manager and Testing personnel) verified that they were unable to locate a procedure or policy for performing and monitoring competency of consultants or testing personnel. 4) Annual test volume for histopathology is 6,160.
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 record review and interview, the laboratory failed to perform twice annual verification of accuracy in the subspeciality of Histopathology for Mohs Surgery (Mohs) twice annually in 2022 and four (PT1-PT3 and PT8) of four patients reviewed for histopathology testing completed in 2022. Findings include: 1) Review of the Enclosure I Methodology Testing List, signed by the laboratory director on 7/10/23, indicated the "Proficiency Program" for histopathology/Mohs slides as "Peer Review." 2) Review of policy and procedure manual indicated the following: a) A letter of agreement between the laboratory director and another medical doctor indicated slide review occurs biannually. The letter contains the signatures of the laboratory director and another medical doctor, but no date. b) There was no documentation of biannual slide review for 2022. c) There was no policy for biannual slide review, how many cases would be reviewed, when the review would occur, or how the results would be evaluated. 3) On 7/11/23 at 1:37pm, SP2 verified there was no "twice annual verification procedure or policy" available to show when and how verification for histopathology slides will be performed. 4) Upon request for documentation of biannual slide review for 2022, on 7/11/23 at 2:15 pm, SP2, verified that they could not locate any records for twice annual verification of accuracy performed in 2022. 5) Review of patient files indicated the following patients had slides reviewed without twice annual verification being performed in 2022: Patient Date of Testing PT1 1/11/2022 PT2 6/2/2022 PT3 10/10/2022 PT8 4/29/2022 6) Annual test volume for histopathology is 6,160.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation, record review, and interview the laboratory failed to ensure hazardous waste/toxic chemicals (Acid Alcohol Decolorizer, 3%, Reagent Alcohol, 100%, Platinum Eosin Y Stain, ExCell Plus, and Hematoxylin 560) were being disposed of down a sink where an eyewash was mounted for one of two eyewashes observed in the laboratory. Findings include: 1. During tour the laboratory on 7/11 /2023 at 10:50 am, the following was observed: a) An eye wash station was observed attached to a faucet in a sink where tubing from running from the "manual slide stainer" into the adjacent sink. b) The list of chemicals being drained into the sink are as follows: -Acid Alcohol Decolorizer, 3% -Reagent Alcohol, 100% (Anhydrous) -Platinum Eosin Y Stain in Alcohol -ExCell Plus -Hematoxylin 560 2. On 7/11/2023 at 10:50 am, SP2 (laboratory manager/testing personnel) confirmed chemicals used in the processing of staining histology slides are disposed of in this sink. 3. Review of Material Safety Data sheets (MSDS) for each chemical indicates the following for the eye: a) "Acid Alcohol Decolorizer, 3%," Section 2 reads; Causes serious eye irritation. Section 4 page 2 of 8 reads; IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. b) "Reagent Alcohol, 100% (Anhydrous)," Section 4 page 2 of 7 reads; Immediately flush with plenty of water for at least 15 minutes, separating eyelids occasionally. Remove contact lenses if present.

	Get immediate medical attention. c) "Platinum Eosin Y Stain in Alcohol," Section 4 page 2 of 7 reads; Immediately flush with plenty of water for at least 15 minutes, separating eye lids occasionally. Remove contact lenses if present. Get immediate medical attention. d) "ExCell Plus," Section 4 page 5 of 10 reads; Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor. e) "Hematoxlin 560," Section 2 page 2 of 10 reads; Causes serious eye irritation, Section 4 page 4 of 10 reads; open eye for several minutes under running water. If symptoms persist, consult a doctor. 5. Annual test volume for histopathology is 6,160.
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 record review and interview, the laboratory failed to ensure one (SP2 Mohs Surgery (Mohs) technician) of two persons performing the duties of a testing personnel (TP) was qualified for high complexity testing (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 record review, and interview, the laboratory failed to ensure one (SP2 Mohs Surgery (Mohs) technician) of two persons performing the duties of a testing personnel (TP) met qualification requirements for high complexity testing from 12/4/2020 to the date of the survey. Findings include: 1. Review of the "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the laboratory director on 7/10/23, indicated SP2 was a testing person. 2. Review of personnel records for SP2 indicated the following: a) "Certificate in Histotechnology" from Indiana University dated May 13, 2023. b) SP2 transcripts from Indiana University, Indianapolis, shows 12 credit hours from "Medicine Undergraduate Program" for histotechnology classes. This does not qualify for high complexity testing personnel. 3. Interviews on 7/11/23 with SP2 indicated: a) At 1:45 pm, SP2 confirmed they perform "grossing " of histology samples. b) At 1:50 pm, SP2 indicated they had recently, 5/13/23, obtained a "Certificate in Histotechnology" from the Indiana University School of Medicine, but transcript provided are the only courses taken, and their hire date is 12/4/20.