Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	08D1091063	01/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Incendium, Llc	1695 S State Street, Suite B, Dover, DE	

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	A Recertification Survey was conducted on January 10, 2022 at approximately 1:30 pm at Delaware Plastic Surgery PA. The laboratory was surveyed according to 42 CFR part 493 CLIA requirements. Specific deficiencies are as follows:
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: based on record review and interview with the Laboratory Director, the laboratory failed to ensure positive identification for one of six patients reviewed. Findings include: 1. At approximately 2:00 pm on January 10, 2022 it was determined that 1 of 6 patient names did not match exactly on the MOHS Micrographic Surgery Map with the Case Log (Patient 200120), having been misspelled on the Case Log, lacking a "t" at the end. It was also determined that the patient's name on the slides corresponded with the Case Log and Map. 2. In an interview at approximately 2:15 pm, the Director confirmed that the patient's name was not the same on the Case Log and the patient's Map.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if

	applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: based on lack of documentation, and interview the laboratory failed to document temperature and humidity ranges to ensure manufacturer's storage requirements. The findings include: 1. The blocks stored in that room must be stored in a temperature-controlled environment. 2. At approximately 2:30 pm on January 10, 2022 during document review of six MOHS Daily Maintenance Logs, it was determined that no acceptable ranges for room temperature or humidity were established or documented. 3. During the interview at approximately 2:40 pm the director confirmed the laboratory failed to monitor and document temperature and humidity as necessary.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: based on observation and interview that reagents were being used by the laboratory beyond their expiration date. 1. At approximately 3:40 pm on January 10, 2022 expired reagents were observed in the laboratory. The director stated that he thought they were alright to use since the daily QC "works". 2. The expired reagents included two of two bottles of Acrymount which expired on 10-22-21, and one bottle of Black Tissue Marking Dye which expired on 12-31-21.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: based on lack of documentation, and interview the laboratory failed to perform competency assessments on testing personnel. The findings include: 1. During record review on January 10, 2022 at approximately 3:00 pm, when reviewing the laboratory's quality manual, no competency assessment policies or procedures were available. 2. Competency assessments were requested by the surveyor for all testing personnel at approximately 3:05 pm. The laboratory was unable to provide

	documentation of competency assessment prior to the end of the survey. 3. During an interview with the laboratory director at approximately 3:10 pm, he confirmed that competency assessment was not being performed for the Technical Supervisor and 2 of 2 Testing Personnel, and that there was no SOP for competency assessment. The laboratory did not provide the record by the end of the survey at 3:30 pm.