Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 39D1084575	**(X3) Date Survey Completed** 09/12/2022
Name of Provider or Supplier Keystone Derm Ctr For Skin Surg Llc	**Street Address, City, State** 2525 9th Avenue Suite 2a, Altoona, PA	
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**
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 review of laboratory records and interview with the Laboratory Supervisor (LS), the laboratory failed to verify the accuracy of the microscopic examinations for 1 of 5 Testing Personnel (TP) for histopathology (Mohs micrographic surgery), mycology (Potassium Hydroxide (KOH)) and parasitology (Scabies) at least twice annually from 07/13/2020 to 09/12/20222. Findings include: 1. On the day of survey, 09/12/2022 at 12:03 pm., Review of Mycology, Scabies, and Mohs micrographic surgery peer review records revealed, the laboratory did not verify twice annually the evaluation and verification activity for the microscopic examinations for histopathology, mycology (KOH) and parasitology (Scabies) in 2020 and 2021 for 1 of 5 TP (CMS 209 Personnel #1) 2. The LS confirmed when interviewed on 09/12 /2022 at 12:03 pm., that no evaluation and verification activity was performed for microscopic examinations for mycology (KOH) and parasitology (Scabies) in 2020 and 2021 for TP#1. 3. The LS confirmed on 09/12/2022 at 12:39 pm., that 1 of 5 TP (TP#1) performed once annually the evaluation and verification for Mohs microscopic examinations in 2020 and 2021. 4. Review of the CMS116 form revealed, the laboratory has an annual tests volume of 50 test performed for Mycology and Parasitology and 2000 tests performed for Histopathology. 5. The LS confirmed the findings above on 09/12/2022 at 01:50 pm.
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 observation of the laboratory and interview with the Laboratory Supervisor (LS), the laboratory failed to monitor and document the temperature of 1 of 1 refrigerator used for the storage of 7 of 7 bottles of immunohistochemical stain materials from 07/13/2020 to the date of survey. Findings include: 1. On the date of survey 09/12/2022 at 12:18 pm., observation of the Histopathology laboratory areas revealed, the 1 of 1 refrigerator that housed the Immunohistochemical stain reagents was not monitored for temperature from 07/13/2020 to 09/12/2022. 2. The refrigerator housed: - 1 of 1 bottle of BioCare Medical Romalin AEC Stabilizer A lot# 102721A-2 expiration date: 04/2023. - 1 of 1 bottle of BioCare Medical Romalin AEC Chromagen B lot# 102721A-2 expiration date: 04/2023. - 1 of 1 bottle of BioCare Medical Romalin AEC Hydrogen Peroxide C lot# 102721A-2 expiration date: 04 /2023. - 1 of 1 bottle of BioCare Medical Background Sniper lot# 082521A expiration date: 08/2023. - 1 of 1 bottle of BioCare Medical Mart-1 cocktail lot# 010322A expiration date: 01/2024. - 1 of 1 bottle of BioCare Medical MACH 2 universal HRP polymer detection lot# 102521A expiration date: 04/2023. - 1 of 1 bottle of BioCare Medical MACH 2 mouse HRP polymer lot# 05022A-2 expiration date: 11/2023. 3. Review of the CMS 116 form revealed, the laboratory has an annual test volume of 2000 tests performed for Histopathology. 4. The LS confirmed the findings above on 09/12/2022 at 01:50 pm.
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 of the Laboratory and interview with the Laboratory Supervisor (LS), the laboratory failed to ensure that 4 of 4 Tissue Marking reagents in histopathology were not used beyond their expiration dates. Findings Include: 1. At the Time of the survey 09/12/2022 at 01:00 pm, during the tour of the laboratory the following 4 of 4 tissue marking reagents were found expired: - Black Tissue Marking Dye Lot 043418 expired 01/18 - Black Tissue Marking Dye lot 053497 expired 04/19 - Blue Tissue Marking Dye lot 056414 expired 07/19 - Red Tissue Marking Dye lot 053794 expired 05/19 2. Review of the CMS 116 form revealed, the laboratory has an annual test volume of 2000 tests performed for Histopathology. 3. The LS confirmed the findings above on 09/12/2022 at 01:50 pm.