Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2205086	(X3) Date Survey Completed 02/07/2023
Name of Provider or Supplier Vitalskin Medical Group Il, P L L C	Street Address, City, State 917 Remington Rd, Mattoon, 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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with mohs technician #1 the laboratory failed to meet the requirements of this condition. The laboratory failed to perform bi-annual method accuracy evaluations for mohs histopathology and frozen histopathology testing in 2021 and 2022 (See D5217). The laboratory failed to perform bi-annual method accuracy evaluations for ectoparasite (scabies) testing in 2021 and 2022 (See D5219).
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: A. Based on review of laboratory records and interview with mohs technician #1; the laboratory failed to perform bi-annual method accuracy evaluations for mohs histopathology testing in 2021 and 2022. Findings Include: 1. Review of the proficiency testing (PT) procedure, "6. Proficiency Testing", stated the following for

	bi-annual method accuracy assessments for mohs histopathology testing: "...our lab maintains quality control by the lab director reviewing 5 randomly selected Mohs cases per half year. the lab director will review these slides/cases and document any findings that are inconsistent with the original findings." 2. Review of PT records found the mohs cases selected as part of the bi-annual mohs PT review were both originally resulted and had the secondary review performed by the laboratory director for four of four review periods. a. Mohs Slide Review Log - Feb-June 2021 b. Mohs Slide Review Log - July-Dec 2021 c. Mohs Slide Review Log - Jan-June 2022 d. Mohs Slide Review Log - Aug-Dec 2022 3. The laboratory performed 453 Mohs cases in 2021 and 485 Mohs cases in 2022. 4. Interview with Mohs technician #1 on 2-07-2023, at 1:15 pm, confirmed the above findings. B. Based on review of laboratory records, lack of documentation and interview with mohs technician #1; the laboratory failed to perform bi-annual method accuracy evaluations for frozen histopathology testing in 2021 and 2022. Findings Include: 1. Review of the proficiency testing (PT) procedure, "6. Proficiency Testing", failed to outline bi-annual method accuracy assessments for frozen histopathology testing. 2. Review of PT records found no bi-annual method accuracy was performed or documented for frozen histopathology testing performed in 2021 and 2022. 3. The laboratory director read 15 frozen pathology slides in 2021 and 31 frozen pathology slides in 2022. 4. Interview with mohs technician #1 on 2-07-2023, at 1:15 pm, confirmed the above findings.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with mohs technician #1; the laboratory failed to perform bi-annual method accuracy evaluations for ectoparasite (scabies) testing in 2021 and 2022. Findings Include: 1. Review of the proficiency testing (PT) procedure, "6. Proficiency Testing", failed to outline bi-annual method accuracy assessments for ectoparasite (scabies) testing. 2. Review of proficiency testing documentation found no evidence of bi-annual method accuracy evaluation for ectoparasite (scabies) testing in 2021 and 2022. 3. The CMS-116 Clinical Laboratory Improvement Amendments (CLIA) application for certification estimates ~30 ectoparasite (scabies) tests performed each year. 4. Interview with mohs technician #1 on 2-07-2023, at 1:15 pm, confirmed the above findings.
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 review of laboratory records and interview with mohs technician #1; the laboratory failed to correctly identify the test performed on the patient test reports for two of two ectoparasite (scabies) examination reports reviewed. Findings Include: 1. Review of two of two patient test reports for ectoparasite (scabies) examinations found the laboratory failed to properly identify the name of the test performed. The laboratory identified the ectoparasite (scabies) examinations as "KOH Preps". Patient Identification Test Date MM0000001910 05-14-2021 MM0000093552 09-26-2022 2. The CMS-116 Clinical Laboratory Improvement Amendments (CLIA) application for certification estimates ~30 ectoparasite (scabies) tests performed each year. 3. Interview with mohs technician #1 on 2-07-2023, at 1:15 pm, confirmed the above findings.