Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0324336	(X3) Date Survey Completed 12/07/2022
Name of Provider or Supplier Dermatology Associates Of Northern Ky Psc	**Street Address, City, State** 7766 Ewing Blvd Ste 100, Florence, KY	

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	On 12/07/2022, a recertification survey was conducted, and the facility was found not to be in substantial compliance with the laboratory requirements at 42 CFR, Part 493. Three deficiencies were cited.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on interviews, document review, and facility policy review, the laboratory failed to ensure that histopathology cases read by 1 of 3 doctors were included in the laboratory's biennial peer review program. Findings included: Review of the laboratory's quality assessment (QA) records revealed a split sample peer review was performed twice per year in June and December between two doctors in the practice (the Laboratory Director [LD] and Doctor #1). During an interview on 12/07/2022 at 2:35 PM, Testing Personnel (TP) #1 stated Doctor #2 (a former employee) would come to the office to read histopathology slides when the LD was on vacation. During an interview on 12/07/2022 at 3:30 PM, the LD stated that random cases performed by the LD and Doctor #1 were selected in June and December of each year for peer review. When asked if cases performed by Doctor #2 were included in the review, the LD stated they were not, because Doctor #2 participated in proficiency testing at their new/current job. Review of the facility's undated policy titled, "Section V: Proficiency Testing," indicated "doctors in a group practice may test each other blindly, as described above, and without assistance from their fellow physicians to fulfill the bi-annual quality assessment requirements for that procedure."

D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interviews and record review, the laboratory failed to document quality control (QC) results for the melanoma-associated antigen recognized by T-cells (MART-1) immunohistochemistry (IHC) performed on 3 (Patients #1, #2, and #3) of 3 patients reviewed. Findings included: During an interview on 12/07/2022 at 4:10 PM, Testing Personnel (TP) #1 stated a QC slide was prepared when the MART-1 IHC was ordered with a case and given to the doctor for interpretation. According to TP #1, the QC result was then documented in the patient's report. The following patient results were reviewed for MART-1 IHC testing and found to have no QC result documented in the report: - Patient #1: date of service 12/05/2022 - Patient #2: date of service 04/21/2022 - Patient #3: date of service 11/01/2022 During an interview with the Laboratory Director and TP #1 on 12/07/2022 at 4:24 PM, both acknowledged the QC result was not documented in the above referenced reports.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on interviews and document review, the laboratory failed to ensure the technical supervisor (TS) documented an annual competency evaluation using the six mandated competency assessment requirements for 1 (Testing Personnel [TP] #1) of 1 testing personnel reviewed. Findings included: Review of an annual competency evaluation, dated 01/05/2022 for TP #1, revealed the evaluation did not address the following six mandated competency assessment requirements: - Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing. - Monitoring the recording and reporting of test results. - Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. - Direct observation of performance of instrument maintenance. - Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. - Assessment of problem-solving skills. During an interview on 12/07/2022 at 3:30 PM, the Laboratory Director (LD) was asked how competency for TP #1 was assessed. The LD replied that the quality of the slides showed competency. During a concurrent document review and interview, the annual competency evaluation for TP #2, dated December 2019, revealed the evaluation addressed all six mandated competency assessment requirements. The LD could not explain why this evaluation was not still being used but stated going forward, this evaluation would be used.