Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0434047	02/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Distinctive Dermatology	390 Office Ct, Fairview Heights, 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 policies, laboratory records; lack of documentation, and interviews with the laboratory director and testing personnel #4; the laboratory: a) failed to provide competency assessments for all tests performed (see D5209); b) failed to perform method accuracy evaluations for histopathology frozen biopsy testing (see D5217); and c) failed to perform bi-annual method accuracy evaluations for scabies wet mount testing (see D5219) for 2022 and 2023.
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 review of laboratory policies, competency records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to provide competency assessments for all tests performed in 2022 and 2023 as required by 493.

	1235. Findings Include: 1. Upon review of the laboratory policies, under "Ongoing assessment", it's stated, "The competency of testing personnel and all staff members will be evaluated and documented annually by the laboratory director or appropriate designated staff member to ensure that all laboratory staff maintain their competency...." 2. Review of competency records found no documented annual competency assessments for "Skin Prep Fungus Evaluation" wet mount testing in 2022 and 2023. 3. Interview with the LD on 02/20/2024, at 2:15 pm, confirmed that the laboratory failed to perform bi-annual method accuracy verifications for scabies wet mount testing in 2022 and 2023.
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 policies, bi-annual method accuracy (proficiency testing) records, lack of documentation and interview with laboratory testing personnel (TP) #4; the laboratory failed to perform method accuracy evaluations for histopathology frozen biopsy testing as required per 493.1236. Findings include: 1. Upon review of laboratory policies, under Proficiency Testing, it's stated, "Proficiency testing is performed on all Dermatopathologists who work within the Dermatopathology Lab at Distinctive Dermatology. Proficiency testing must be performed bi-annually. Slides will be selected at random and sent to another CLIA certified laboratory for outside review...." 2. Review of laboratory records revealed a lack of bi-annual method accuracy records for histopathology frozen biopsy testing for any of Distinctive Dermatology's dermatopathologists. 3. Review of patient testing logs revealed seven histopathology frozen biopsies in 2022 and four histopathology frozen biopsies in 2023. Case #: Date: 2201 02/17/2022 2202 02/21/2022 2203 05/04 /2022 2204 07/06/2022 2205 07/21/2022 2206 08/15/2022 2207 08/16/2022 2301 04 /18/2023 2302 07/24/2023 2303 10/23/2023 2304 10/23/2023 4. Review of two randomly selected histopathology frozen biopsy patients reports (Case #s 2203 and 2302) revealed both specimens were "processed by frozen section in [Distinctive Dermatology's] Mohs laboratory" and resulted by TP #4. 5. An interview with TP #4 at 1:51 pm on 02/20/2024 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 policies and records, and interview with laboratory director (LD); the laboratory failed to perform bi-annual method accuracy evaluations for four of four scabies wet mount testing occasions in 2022 and 2023 as required by 493.1236. Findings Include: 1. Upon review of the laboratory's "Skin Prep for Scabies" procedure, under "Proficiency Testing", it's stated, "At least twice annually, at least two providers will have blind confirmation of their diagnosis. In January and

	July it will be noted that this proficiency testing has been performed and will be logged in the proficiency log." 2. Review of proficiency testing records found no documented bi-annual method accuracy evaluations for four of four scabies wet mount testing occasions in 2022 and 2023. 3. Interview with the LD on 02/20/2024, at 2:15 pm, confirmed that the laboratory failed to perform bi-annual method accuracy verifications for scabies wet mount testing in 2022 and 2023.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory policies, lack of documentation, patient testing logs, patient test results, and interview with laboratory director (LD); the laboratory failed to have a procedure manual in place for all tests performed as required per 493. 1251. Findings Include: 1. Upon review of the laboratory's policies, under "Procedure manual", it's stated, "The procedure manual will be modified as needed to reflect the current practices of the laboratory." 2. Review of the laboratory's procedure manual revealed the lack of a procedure for histopathology frozen biopsies. 3. Review of patient testing logs revealed seven histopathology frozen biopsies in 2022 and four histopathology frozen biopsies in 2023. Case #: Date: 2201 02/17/2022 2202 02/21 /2022 2203 05/04/2022 2204 07/06/2022 2205 07/21/2022 2206 08/15/2022 2207 08 /16/2022 2301 04/18/2023 2302 07/24/2023 2303 10/23/2023 2304 10/23/2023 4. Review of two randomly selected frozen biopsy patients reports (Case #s 2203 and 2302) revealed both specimens were "processed by frozen section in [Distinctive Dermatology's] Mohs laboratory" and resulted. 5. An interview with LD at 2:45 pm on 02/20/2024 confirmed the above findings.