Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2077428	05/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Specialists Of Canton	361 N Canton Center Rd, Canton, MI	

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
D5006	MYCOLOGY CFR(s): 493.1203 If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on observation, record review, and interviews, the laboratory failed to establish competency assessment policies and procedures for staff performing direct wet mount preparations for presence of parasites (refer to D5209 B), to verify accuracy of direct wet mount preparations for presence of parasites at least twice annually (refer to D5217 B), and to establish procedures for performance of direct wet mount preparations for presence of parasites (refer D5401 B).
D5008	PARASITOLOGY CFR(s): 493.1204 If the laboratory provides services in the subspecialty of Parasitology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1264, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on observation, record review, and interviews, the laboratory failed to establish competency assessment policies and procedures for staff performing Potassium Hydroxide Testing (refer to D5209 A), to verify accuracy of Potassium Hydroxide preparations (KOH) at least twice annually (refer to D5217 A), and to establish procedures for performance of Potassium Hydroxide preparations (KOH) (refer to D5401).

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: . A. Based on observation, record review, and interview, the laboratory failed to establish competency assessment policies and procedures for staff performing Potassium Hydroxide Testing for two (May 2022 - May 2024) of two years reviewed. Findings include: 1. The surveyor observed a microscope and chlorazol black stain, used in KOH testing, in the laboratory on 5/15/24 at 12:03 pm. 2. A review of the laboratory records revealed the lack of competency assessment procedures for personnel performing KOH testing and competency assessments for testing personnel #2 and #3 that performed KOH Testing between May 2022 and May 2024. 3. A review of the laboratory procedure titled "Regulatory Overview" stated "Personnel Competency Assessment Polices. The laboratory must establish and follow written policies and procedures to assess the competency of employees and if applicable consultants." 4. A request for competency assessments for KOH Testing were made to the Medical Assistant on 5/15/24 at 2:25 pm and documents were not made available. 5. An interview on 5/15/24 at 2:25 pm with Medical Assistant confirmed that competency assessments were not performed. B. Based on observation, record review, and interview, the laboratory failed to establish competency assessment policies and procedures for staff performing direct wet mount preparations for presence of parasites for two (May 2022 - May 2024) of two years reviewed. Findings include: 1. The surveyor observed a microscope in the laboratory on 5/15/24 at 12:03 pm. 2. An interview with the Medical Assistant on 5/15/24 at 12:04 pm revealed that the microscope was used for direct wet mount preparations for presence of parasites. 3. A review of the laboratory records revealed the lack of competency assessment procedures for personnel performing direct wet mount preparations for presence of parasites and competency assessments for testing personnel #2 and #3 that performed direct wet mount preparations for presence of parasites between May 2022 and May 2024. 4. A review of the laboratory procedure titled "Regulatory Overview" stated "Personnel Competency Assessment Polices. The laboratory must establish and follow written policies and procedures to assess the competency of employees and if applicable consultants." 5. A request for competency assessments for direct wet mount preparations for presence of parasites were made to the Medical Assistant on 5/15/24 at 2:25 pm and documents were not made available. 6. An interview on 5/15/24 at 2: 25 pm with Medical Assistant confirmed that competency assessments were not performed.
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 observation, record review, and interview, the laboratory failed to verify accuracy of Potassium Hydroxide preparations (KOH) at least twice annually for two

	(May 2022 - May 2024) of two years reviewed. Findings include: 1. The surveyor observed a microscope and chlorazol black stain, used in KOH testing, in the laboratory on 5/15/24 at 12:03 pm. 2. A review of the laboratory records revealed the lack of verification of accuracy documentation for KOH testing was not present for May 2022 - May 2024. 3. An interview conducted on 5/15/24 at 2:35 pm with the Medical Assistant which confirmed verification of accuracy was not performed. B. Based on observation, record review, and interview, the laboratory failed to verify accuracy of direct wet mount preparations for presence of parasites at least twice annually for two (May 2022 - May 2024) of two years reviewed. Findings include: 1. The surveyor observed a microscope in the laboratory on 5/15/24 at 12:03 pm. 2. An interview with the Medical Assistant on 5/15/24 at 12:04 revealed that the microscope was used for direct wet mount preparations for presence of parasites. 3. A review of the laboratory records revealed the lack of verification of accuracy documentation for direct wet mount preparations for presence of parasites was not present for May 2022 - May 2024. 4. An interview conducted on 5/15/24 at 12:50 pm with the Medical Assistant revealed that about five patients were tested in the past two years. 5. An interview conducted on 5/15/24 at 2:35 pm with the Medical Assistant which confirmed verification of accuracy was not performed.
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: . A. Based on observation, record review, and interview, the laboratory failed to establish procedures for performance of Potassium Hydroxide preparations (KOH) for two (May 2022 - May 2024) of two years reviewed. Findings include: 1. The surveyor observed a microscope and chlorazol black stain, used in KOH testing, in the laboratory on 5/15/24 at 12:03 pm. 2. A review of the laboratory records revealed the lack of procedures for KOH testing. 3. An interview conducted on 5/15/24 at 12:50 pm with the Medical Assistant revealed that about five patients were tested in the past two years. 4. An interview conducted 5/15/24 at 2:26 pm with the Medical Assistant revealed the laboratory did not have policies and procedures for conducting testing. B. Based on observation, record review, and interview, the laboratory failed to establish procedures for performance of direct wet mount preparations for presence of parasites for two (May 2022 - May 2024) of two years reviewed. Findings include: 1. The surveyor observed a microscope in the laboratory on 5/15/24 at 12:03 pm. 2. An interview with the Medical Assistant on 5/15/24 at 12:04 revealed that the microscope was used for direct wet mount preparations for presence of parasites. 3. A review of the laboratory records revealed the lack of procedures for direct wet mount preparations for presence of parasites. 4. An interview conducted on 5/15/24 at 12:50 pm with the Medical Assistant revealed that about five patients were tested in the past two years. 5. A record review of Patient A's chart from 04/05/24 revealed a microscopic skin examination was conducted and stated, "Looked under a microscope and it looked consistent with bed bugs." 6. An interview conducted 5/15/24 at 2:26 pm with the Medical Assistant revealed the laboratory did not have policies and procdures for conducting direct wet mount preparations for presence of parasites.

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, interview, and record review, the laboratory failed to ensure that 95% Reagent Alcohol was not used beyond the expiration date for one bottle observed. Findings include: 1. The surveyor observed one bottle of 95% Reagent Alcohol with the expiration date of 3/31/23 on 5/15/24 at 11:48 am. 2. An interview was conducted on 5/15/24 at 12:01 pm with the Medical Assistant and confirmed the 95% Reagent Alcohol was expired. 3. The surveyor reviewed the Laboratory's "Regulatory Overview" policy and revealed a section titled "Reagents, Materials and Supplies" stating, "No reagent, solution, mediates or materials should be used after their expiration date."
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on observation, record review, and interviews, the Laboratory Director failed to assure compliance with the notification requirements for laboratories issued a certificate of compliance (refer to D6004), failed to ensure quality assessment programs were maintained to monitor the quality of mycology and parasitology testing (refer to D6021), failed to ensure verification of accuracy testing was performed at least twice annually for Potassium Hydroxide preparations (KOH) (refer to D6023 A), failed to ensure verification of accuracy testing was performed at least twice annually for direct wet mount preparations for presence of parasites (refer to D6023 B), failed to ensure competency assessment policies and procedures were established for staff performing Potassium Hydroxide Testing (refer to D6030 A), failed to ensure competency assessment policies and procedures were established for staff performing direct wet mount preparations for presence of parasites (refer to D6030 B), failed to ensure procedures for performance of Potassium Hydroxide preparations (KOH) were established (refer to D6031 A), and failed to ensure procedures for performance of direct wet mount preparations for presence of parasites were established (refer to D6031 B).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical

	consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Medical Assistant, the Laboratory Director failed to assure compliance with the notification requirements for laboratories issued a certificate of compliance for 2 (May 2022 to May 2024) of 2 years reviewed. Findings include: 1. The surveyor observed a microscope and chlorazol black stain, used in Potassium Hydroxide (KOH) testing, in the laboratory on 5/15/24 at 12:03 pm. 2. An interview with the Medical Assistant on 5/15/24 at 12:04 revealed that the microscope was used for direct wet mount preparations for presence of parasites and KOH testing. 3. A review of the laboratory's Form CMS-116 and previous notifications to the State Agency revealed a lack of documentation adding both Mycology and Parasitology subspecialty testing in accordance with 493.51 Notification requirements for laboratories issued a certificate of compliance, which states, "Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in-- (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity only). (b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined. (c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance." 4. An interview on 5/15/24 at 2:28 pm with the Medical Assistant confirmed the Laboratory Director did not notify the State Agency of the addition of testing specialties in accordance with 493.51 Notification requirements for laboratories issued a certificate of compliance.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: . Based on record review and interview with the Medical Assistant, the Laboratory Director failed to ensure quality assessment programs were maintained to monitor the quality of mycology and parasitology testing for 2 (May 2022 to May 2024) of 2 years reviewed. Findings include: 1. The surveyor observed a microscope and chlorazol black stain, used in Potassium Hydroxide (KOH) testing, in the laboratory on 5/15/24 at 12:03 pm. 2. An interview with the Medical Assistant on 5/15/24 at 12:04 revealed that the microscope was used for direct wet mount preparations for presence of parasites and KOH testing. 3. A review of the laboratory's "Quality Assessment Procedures" revealed a section stating, "To ensure the testing of patient samples and

	reporting of test results are performed accurately and in compliance with applicable regulations, the Hamzavi Dermatology Clinic Laboratory maintains a Quality Assessment (QA) program that monitors preanalytic, analytic, and postanalytic activities." 4. A review of the laboratory's "Quality Assurance Checklists" from June 2022 to December 2023 revealed a lack of documentation of quality assessment activities for KOH and Scabies testing. The document had these tests crossed off with a line through "KOH" and "Fungal" and had "N/A" written on the side. 5. An interview on 5/15/24 at 2:27 pm with the Medical Assistant confirmed the laboratory did not perform quality assessments for its KOH and direct wet mount preparations for presence of parasites.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: A. Based on observation, record review, and interview, the Laboratory Director failed to ensure verification of accuracy testing was performed at least twice annually for Potassium Hydroxide preparations (KOH). Refer to D5217 A. B. Based on observation, record review, and interview, the Laboratory Director failed to ensure verification of accuracy testing was performed at least twice annually for direct wet mount preparations for presence of parasites. Refer to D5217 B.
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: . A. Based on observation, record review, and interview, the Laboratory Director failed to ensure competency assessment policies and procedures were established for staff performing Potassium Hydroxide Testing. Refer to D5209 A. B. Based on observation, record review, and interview, the Laboratory Director failed to ensure competency assessment policies and procedures were established for staff performing direct wet mount preparations for presence of parasites. Refer to D5209 B.

D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: . A. Based on observation, record review, and interview, the Laboratory Director failed to ensure procedures for performance of Potassium Hydroxide preparations (KOH) were established. Refer to D5401 A. B. Based on observation, record review, and interview, the Laboratory Director failed to ensure procedures for performance of direct wet mount preparations for presence of parasites were established. Refer to D5401 B.