Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0868799	(X3) Date Survey Completed 05/12/2021
Name of Provider or Supplier Heidelberg Dermatology Pc	**Street Address, City, State** 20400 Livernois Avenue, Detroit, 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 record review and interview with the Practice Administrator (PA), the laboratory failed to meet the subspecialty of mycology requirements as specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to perform and document the microscope maintenance. Refer to D5429. 2. The laboratory failed to perform and document the refrigerator temperature that houses the dermatophyte test media. Refer to D5431. 3. The laboratory failed to perform and document the quality control for the dermatophyte test media (DTM) with the appropriate organisms with each new lot number and/or shipment . Refer to 5519 4. The laboratory failed to monitor and evaluate the analytic system assessment activities. Refer to D5793
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on record review and interview with the Practice Administrator (PA), the laboratory failed to perform and document the microscope maintenance as required

	for 1 (2020) of 2 years reviewed. Findings include: 1. A review of the "Laboratory Procedure Manual" under the "Quality Control" section, the laboratory is to have the microscope cleaned every 6 months. 2. A record review of the microscope maintenance revealed for 1 (2020) of 2 years reviewed a lack of documentation as follows: a. lack of documentation for June 2020 cleaning b. lack of documentation for December cleaning 3. An interview on 5/12/2021 at 9:52 am, the PA confirmed the microscope cleaning was not performed in 2020.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on lack of documentation and interview with the Practice Administrator (PA), the laboratory failed to perform and document the refrigerator temperature that houses the dermatophyte test media each day of operation for 3 months (December 2020 and March and April 2021) of 2 years reviewed. Findings include: 1. Record review of the "Equipment Quality Control" log sheet revealed for 3 months (December 2020 and March and April of 2021) of 2 years reviewed a lack of documentation of the refrigerator temperature as follows: a. December 2020 - lack of documentation, 23 days b. March 2021 - lack of documentation, 23 days c. April 2021 - lack of documentation, 18 days 2. An interview on 5/12/2021 at 10:30 am, the PA confirmed the lack of documentation of the temperature for the refrigerator during the above listed months.
D5519	MYCOLOGY CFR(s): 493.1263(b)(c) (b)For antifungal susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antifungal agent(s) before, or concurrent with, initial use, using an appropriate control organism(s). (b)(1) The laboratory must establish limits for acceptable control results. (b)(2) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(3) The results for the control organism(s) must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on record review and interview with the Practice Administrator (PA), the laboratory failed to perform and document the quality control for the dermatophyte test media (DTM) with the appropriate organisms with each new lot number and/or shipment for 11 months (July 2020 to May 2021) of 2 years reviewed. Findings include: 1. Review of the "Fungal Culture Logbook" revealed "Fungal Cultures" procedure, step #2, "All new lot numbers are to be tested with positive and negative controls. A copy of the test will be maintained in the Fungal Culture Logbook." 2. Record review of the "Fungal Culture Controls" log revealed for 11 months (July 2020 to May 2021) of 2 years reviewed the laboratory did not perform and document

	quality control for the new lot number and/or shipment of media received as follows: a. 7/31/2020 lot #917802 - lack of documentation of the results for the positive and negative controls. b. 5/12/2021 lot #231583, the current lot in use - lack of documentation for performing controls on the shipment of media. 3. An interview on 5 /12/2021 at 11:04 am the PA confirmed there was no documentation on the log to show that quality control was performed on the new lot number and/or shipment of DTM.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Based on record review and interview with the Practice Administrator (PA), the laboratory failed to monitor and evaluate the analytic system assessment activities for 1 (2020) of 2 years reviewed. Findings include: 1. Record review of the analytic assessment activities revealed for 1 (2020) of 2 years reviewed, a lack of documentation as follows: a. review of the "Quality Assurance Checklist" - lack of documentation for 2020 b. review of the patient chart review - lack of documentation for 2020 2. When queried on 5/12/2021 at 11:07 am, the PA was unable to provide the surveyor the requested documentation. 3. An interview on 5/12/2021 at 11:07 am, the PA confirmed the analytic assessment were not performed and documented.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on record review and interview with the Practice Administrator (PA), the laboratory failed to evaluate the competency of testing personnel (TP) performing the potassium hydroxide (KOH) and dermatophyte test media (DTM) for 2 (TP2 and TP3) of 3 TP listed on the CMS-209 form. Findings include: 1. A record review of the competency assessments revealed for 2 (TP2 and TP3) of 3 TP a lack of documentation as follows: a. TP2 - lack of documentation for the KOH in 2021 b. TP3 - lack of documentation for the DTM in 2021 2. An interview on 5/12/2021 at 10: 05 am, the PA confirmed the competency assessments were not performed and documented in 2021. ***Repeat Deficiency from 9/01/2016 survey***