Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0868799	03/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Heidelberg Dermatology Pc	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
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #3 and #4 (TP3 and TP4), the laboratory failed to have an electronic request for patient testing from an authorized person for the routine mycology fungal culture testing for one (#20) of 20 patient charts audited. Findings include: 1. Record review revealed the laboratory did not have an electronic request for the fungal culture in the patient's electronic medical record (EMR) for patient chart audit #20. 2. During the interview on March 11, 2019 at approximately 11:00 AM, TP4 was unable to find the request for the fungal culture in the patient's EMR file.
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 manufacturer's instruction, record review, and interview with testing personnel #3 and #4 (TP3 and TP4), the laboratory failed to follow the "Troy DTM Media" section of the "CLIA Manual" for interpreting dermatophyte testing media (DTM) culture readings within "14 days of inoculation" or did not include a date of

	interpretation for four (#11 -#12, #15, and #18) of 20 patient charts audited. Findings include: 1. Manufacturer's instructions for the Troy DTM media stated "Dermatophytes produce typical morphology and a pink to red color in the medium surrounding the colony within 10-14 days of incubation. Disregard any color changes in the medium after 14 days of incubation." 2. Record review of patient final results revealed 1) patient test results were reported greater than the 14 day incubation and 2) no date was recorded in the log book to compare against the 14 days following manufacturer's instructions as follows: a. read greater than 14 days 1. patient #11 - read at 29 days 2. patient #12 - read at 39 days 3. patient #18 - read at 31 days b. no result written in log book 1. patient #15 - result entered into EMR at 42 days 3. During the interview on March 11, 2019 at approximately 11:00 AM, TP4 acknowledged that results were not written in the log book and result reading was interpreted greater than the 14 days specified in the "CLIA Manual" and the manufacturer's instructions.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #3 and #4 (TP3 and TP4), the laboratory failed to document corrective action for improper storage of the Troy Biologics Dermatophyte Test Media for the fungal testing for 14 (1-2, 5-7, 11-15, 18-19, 21, and 22) of 22 days of operation in June 2018. Findings include: 1. Record review of the "Equipment Quality Control Form 18: Room and Temperature Log Sheet" revealed for 14 of 22 days in June of 2018 the temperature was below the stated range of 36-46 degree F as follows: a. 34 degrees F - June 11-14, 18 b. 35 degrees F - June 1-2, 5-7, 15, 19, 21-22 2. During the interview on March 11, 2019 at 9:50 AM, TP3 and TP4 confirmed no corrective action was taken for the temperatures outside the stated range. ***Repeat Deficiency from September 1, 2016 survey***
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #3 and #4 (TP# and TP4), the laboratory failed to establish a system to ensure the manually recorded patient test results from the specimen log book were entered correctly into the patient's electronic medical record (EMR) for five (#11, #13, #14, #16, and #18,) of

	20 patient charts audited. Findings include: 1. Record review of the patient's final results in the EMR system showed different result dates from the log book entry as follows: a. Patient #11 log book - finalized April 22, 2017 EMR result - finalized April 24, 2017 b. Patient #13 log book - finalized August 28, 2017 EMR result - September 12, 2017 c. Patient #14 log book - finalized October 17, 2017 EMR result - October 20, 2017 d. Patient #16 log book - February 26, 2018 EMR result - February 19, 2018 e. Patient #18 log book - finalized July 6, 2018 EMR result - July 10, 2018 2. On March 11, 2019 at approximately 12:10 PM, interview with TP4 confirmed that discrepancies exist between the final report dates in the EMR system compared to the final result dates in the laboratory log book.
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 record review and interview with testing personnel #3 and #4 (TP3 and TP4), the laboratory failed to have the final mycology report in the patient's electronic medical record (EMR) for three (#10, #17, and #19) of 20 patient charts audited. Findings include: 1. Record review of the patient's EMR results revealed the laboratory did not have any documentation of the patient's results for the mycology testing in the EMR system as follows: a. patient #10 - no potassium hydroxide results b. patient #17 - no dermatophyte testing media (DTM) results b. patient #19 - no DTM results 2. During the interview on March 11, 2019 at approximately 11:05 AM, TP4 confirmed there was no documentation in the EMR system for the mycology testing ordered.