Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0954489	11/09/2020
Name of Provider or Supplier	**Street Address, City, State**	
Dermatologists Of Southwest Ohio	2500 W Strub Rd, Ste 330, Sandusky, OH	

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
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 record review and interviews with the Office Manager and Head Nurse, the laboratory failed to follow policies and procedures to verify the accuracy of the potassium hydroxide (KOH) and scabies testing, at least twice annually for 4 out of 4 Testing Personnel (TP). All patients tested in the subspecialties of mycology and parasitology had the potential to be affected. Findings include: 1. Review of the laboratory's 'Scabies and KOH Testing Policy and Procedure,' found the following statement:"...Providers performing microscopic testing are assessed semi-annually to assess...test accuracy verification..." 2. Review of the laboratory's KOH and scabies test accuracy verification documentation found that the laboratory failed to follow policies and procedures to assess 4 out of 4 Testing Personnel (TP) for test accuracy verification (TAV) of the KOH and scabies test on a semi-annual basis. TP #3: 2020 Dates: None 2019 Dates: 01/03/2019 2018 Dates: 05/17/2018, 12/28/2018 TP #4: 2020 Dates: None 2019 Dates: 03/19/2019 2018 Dates: 09/07/2018 TP #5: 2020 Dates: None 2019 Dates: 09/07/2018 2018 Dates: 01/03/2018, 10/01/2018 TP #6: 2020 Dates: None 2019 Dates: 02/11/2019, 01/28/19 2018 Dates: 08/03/18 3. An interview with the Office Manager and Head Nurse, on 11/09/2020 at 12:58 PM, confirmed that the laboratory failed to follow their own policy of assessing the providers semi-annually for TAV of the KOH and scabies tests.
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 record review, and interviews with the Office Manager and the Head Nurse, the laboratory failed to follow their policy and procedure, and document microscope cleaning and/or maintenance after 08/18/2020. Nine out of 9 patients tested tested for fungal organisms using the KOH reagent, from 08/19/2020 through 11/09/2020 had the potential to be affected. Findings Include: 1. Review of the laboratory's 'Microscope Maintenance' policy and procedure, on 11/09/2020 at 1:46 PM, found the following statements: "...Procedure: Daily: - Eyepieces and objectives will be cleaned with lens paper or lens cleaner. - Clean stage with lens paper. Remove residual coverslip medium that may accumulate on the stage. - Routine maintenance, problems and corrective actions are recorded on the Microscope Maintenance Log sheet. - The technician completes the Microscope Maintenance Log." 2. Review of the laboratory's 'Microscope- Cleaning/Maintenance for PM Testing - KOH/Scabies' log failed to find any daily microscope cleaning and/or maintenance documented after 08/18/2020. 3. Review of the laboratory's 'KOH Quality Control Log' found 9 patients tested for fungal organisms using the KOH reagent after 08/18/20, without any documented daily microscope cleaning and/or maintenance: Patient: Date Tested: 1 08/25/2020 2 08/27/2020 3 09/02/2020 4 09/09/2020 5 09/08/2020 6 09/16/2020 7 10/14/2020 8 10 /20/2020 9 10/29/2020 4. An interview with the Office Manager and Head Nurse, on 11/09/20 at 1:48 PM, confirmed that the laboratory failed to follow their policy and procedure, and document daily microscope cleaning and/or maintenance for 9 patients tested, after 08/18/2020, for fungal organisms with the KOH reagent.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, and an interview with Testing Personnel #4 (TP #4), the Office Manager and the Head Nurse, the laboratory failed to perform, document and follow QC (quality control) procedures for the potassium hydroxide (KOH) and scabies testing performed to detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance, for 5 out of ninety-seven patients tested from 08/29/2018 through 11/09/2020. Findings Include: 1. Review of the laboratory's 'KOH Testing Policy and Procedure' found the following statement: "...Quality Control Testing 1. A Quality Control (QC) slide will be performed on the first KOH test of the day and recorded in the KOH QC Log. The

	provider performs the same KOH test procedure steps as listed above and reads both slides. Record the date and patient name in the QC log. The specimen is divided into two slides (slide #1 and slide #2). The results are observed by the provider and written in the Slide 1 Result and Slide 2 Result respectively. If the results of the two slides are the same, the test will be marked as "Y" for Yes in the Test Acceptable column on the KOH Quality Control Log will count as the completion of the Daily QC for that date. If the provider's results of the two slides are not the same, a "N" for No will be recorded in the Test Acceptable Column, a corrective action form will be filled out and a new QC test will be performed before proceeding with any patient KOH testing." 2. Review of the laboratory's 'Daily Patient Log for KOH and Scabies' found 5 out of ninety-seven patients did not have a corresponding QC result, recorded in the 'KOH Quality Control Log' for that day of testing, per the policy. Patient Test Date QC Result 1 10/08/2020 None 2 07/28/2020 None 3 07/29/2020 None 4 03/20/2019 None 5 01/28/2019 None 3. An interview with TP #4 revealed that they do not routinely perform a KOH or scabies QC slide prior to testing patient specimens. 4. An interview with the Office Manager and Head Nurse, on 11/09/2020 at 1:35 PM, confirmed that the laboratory failed to perform, document and follow QC procedures for 5 out of ninety-seven patients.
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: Item I: Based on record review and interviews with the Office Manager and Head Nurse, the laboratory failed to have an adequate manual system in place to ensure the potassium hydroxide (KOH) test result was accurately and reliably transcribed from the patient log to the final test report. Two out of twenty-five patient log results and corresponding final test reports reviewed were affected by this deficient practice. Findings Include: 1. Review of the laboratory's 'KOH Testing Policy and Procedure' found the following statements: "Documentation: 1. Record the date of the test, the patient's name, the patient's Date of Birth (DOB), the test name: KOH, and the site on the Daily Patient Log. 2. Assess the need for QC test and record a QC test if applicable (first slide of the day). See Quality Control Testing 3. Record KOH results in daily log and the patient's chart..." 2. Review of twenty-five patient final test reports and daily patient log results found that the laboratory failed to accurately transcribe 2 patient results from the daily log to the final report. Patient #1: 09/19/2018 Daily Log Result: "Branching hyphae" Final Report Result: "clustered spores and short wide hyphae" Patient #2: 08/14/2019 Daily Log Result: "Spores and branching hyphae" Final Report Result: "Budding yeast with branching hyphae" 3. Interviews with the Office Manager and Head Nurse, on 11/09/2020 at 1:35 PM, confirmed that the laboratory failed to accurately transcribe 2 patient results from the daily log to the final report. Item II: Based on record review and interviews with the Office Manager and Head Nurse, the laboratory failed to have an adequate manual system in place to

	ensure the potassium hydroxide (KOH) specimen source was accurately and reliably transcribed from the patient log to the final test report. Two out of twenty-five patient log and corresponding final test reports reviewed were affected by this deficient practice. Findings Include: 1. Review of the laboratory's 'KOH Testing Policy and Procedure' found the following statements: "Documentation: 1. Record the date of the test, the patient's name, the patient's Date of Birth (DOB), the test name: KOH, and the site on the Daily Patient Log. 2. Assess the need for QC test and record a QC test if applicable (first slide of the day). See Quality Control Testing 3. Record KOH results in daily log and the patient's chart..." 2. Review of twenty-five patient final test reports and daily patient logs found that the laboratory failed to accurately transcribe 2 patient specimen sites from the daily log to the final report. Patient #1: 09/18/2018 Daily Log Specimen Site: "Buttock" Final Report Specimen Site: "right buttock" Patient #2: 04/09/2019 Daily Log Specimen Site: "L rad. dorsal hand" Final Report Specimen Site: "Left radial dorsal hand" and "right medial plantar midfoot" 3. Interviews with the Office Manager and Head Nurse, on 11/09/2020 at 1:35 PM, confirmed that the laboratory failed to accurately transcribe 2 patient specimen sites from the daily log to the final report.