

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0362814	(X3) Date Survey Completed 08/14/2019
Name of Provider or Supplier Dermatology Associates, P C	Street Address, City, State 800 S Adams Suite 101, Birmingham, 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	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the office manager, the laboratory failed to have an electronic request for patient testing from an authorized person for the mycology dermatophyte test medium (DTM) testing for one (31220) of ten patient charts audited. Findings include: 1. Record review for one (31220) of ten patient charts audited revealed the laboratory failed to have an electronic request for the DTM testing in the laboratory's electronic medical record (EMR) system. 2. During the interview on August 14, 2019 at 10:58 a.m., the office manager confirmed no electronic request for the patient testing was in the EMR system. ***Repeat Deficiency from January 18, 2017 survey***</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the office manager, the laboratory failed to follow the manufacturer's instructions for the interpretation of the dermatophyte test medium (DTM) pathogenic fungi isolation for eight (#1, #2, 1615315, 134570, #7,</p>

851, 31220, and 171) of ten patient charts audited. Findings include: 1. The manufacturer's package instructions state "Disregard any color changes in the medium after 14 days of incubation." 2. Record review for eight (#1, #2, 1615315, 134570, #7, 851, 31220, and 171) of ten patient charts audited revealed the final day of interpreting test results exceeded 14 days, of the ten two showed a positive color change as follows: a. #1 - final result read on day 62. b. #2 - final result read on day 23 (positive result recorded). c. 1615315 - final result read on day 38. d. 134570 - final result read on day 56. e. #7 - final result read on day 45. f. 851 - final result read on day 36. g. 31220 - final result read on day 20. h. 171 - final result read on day 21 (positive result recorded). 3. During the interview on August 14, 2019 at approximately 11:00 a.m., the office manager confirmed the test results were recorded after the manufacturer's instructions stated length of time for interpretation.

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 the office manager, the laboratory failed to establish a system to ensure the manually transcribed results for the dermatophyte test medium (DTM) are entered into the electronic medical record (EMR) system with the date the final reading took place for three (123310, 22291, and 851) of ten 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 123310 log book - finalized March 22, 2018 EMR result - finalized July 26, 2018 b. Patient 22291 log book - finalized July 3, 2018 EMR result - July 26, 2018 c. Patient 851 log book - finalized March 19, 2019 EMR result - March 22, 2019 2. During the interview on August 14, 2019 at approximately 11:00 a.m., the office manager confirmed the date of final resulting in the log book did not match with the date in the EMR system.