Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0997107	11/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Anne Arundel Dermatology Pa	600 Ridgely Ave #120, Annapolis, MD	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the laboratory's patient log and interview with the laboratory staff, the laboratory did not establish and follow policies and procedures to ensure positive identification of dermatophyte (DTM) specimens from the time of collection through completion and reporting of patient results. Findings: 1. Specimens collected for DTM testing are documented on a patient log upon receipt into the laboratory. 2. A review of patient logs from 12/8/16 to 10/18/18 showed that 23 of 29 patients did not include a unique patient identifier to ensure positive identification and optimum specimen integrity from the time of collection through result reporting. 3. During an interview on 11/21/18 at 9:45 AM, the laboratory staff confirmed that a unique second identifier is not currently documented on the patient log for DTM specimens received into the laboratory.
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 quality control (QC) record review and interview with the laboratory staff, the laboratory failed to ensure that the expiration dates of media used for dermatophyte testing were documented. Findings: 1. The laboratory performs dermatophyte testing using Acuderm Dermatophyte Test Media. The laboratory saves the "Certificate of Conformity Quality Control" sheets included with each shipment of dermatophyte test media which attests that QC has been performed on each batch of media. 2. A review of "Certificate of Conformity Quality Control" sheets from 2017 and 2018 showed that there was only one sheet available at the time of the survey. 3. During an interview on 11/21/18 at 9:45 AM, the laboratory staff confirmed that expiration dates were not documented for media used for dermatophyte testing.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on temperature log record review and interview with laboratory staff, the laboratory failed to document corrective action when refrigerator temperatures were out of range. Findings: 1. The laboratory utilizes two refrigerators to store dermatophyte media. The temperature range for the laboratory refrigerators is 35 - 41 degrees Fahrenheit; and 2. A review of temperature records from January to December, 2017 showed that "Fridge #1's" temperatures were out of range 235 out of 250 times recorded, and that "Fridge #2's" temperatures were out of range 7 out of 246 times recorded. 3. There were no corrective actions documented for the days that temperatures were out of range. 4. During an interview on 11/21/18 at 9:45 AM, the laboratory staff confirmed that there were no corrective actions documented for the days that the refrigerator temperatures were out of range.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM), and patient log and electronic medical record (EMR) review and interview with laboratory staff, the laboratory staff failed to follow the laboratory's SOPM for reading dermatophyte testing media (DTM) at the proper time. Findings: 1. The procedure "Dermatophyte Testing Medium (DTM)" in the SOPM states that "No DTM will be read after the 14th day due to a marked increase in false positives." The "DTM LOG" includes a

	column for "Date of Results Reading" to record the date that the DTM media is read and the result recorded. 2. A review of patient log records from 12/8/16 to 10/18/18 showed that 24 of 29 patients recorded had their DTM test read after 14 days incubation; and 3. Two of 29 patients did not have a date recorded under "Date of Results Reading." 4. A review of the patient log and EMR showed that 2 of 29 patients' results were recorded on the patient log but not entered in to the EMR. Patient #1's DTM was inoculated on 10/12/18 and was read and resulted on 10/31/18 as positive but there was no record of the result in the EMR; Patient #2's DTM was inoculated on 10/18/18 and was read and resulted on 11/2/18 as negative but there was no record of the result in the EMR. 5. During an interview on 11/21/18 at 9:45 AM, the laboratory staff confirmed that testing personnel did not follow the laboratory's SOPM for reading DTM at the appropriate time and that patient results were not entered into the EMR.