

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1090086	(X3) Date Survey Completed 10/23/2018
Name of Provider or Supplier Anne Arundel Dermatology Pa	Street Address, City, State 180 Admiral Cochrane Dr #410, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) review and interview with laboratory staff, the laboratory did not establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. Findings: 1. Record review showed that the laboratory's SOPM did not include a quality assessment (QA) procedure; and 2. During an interview on 10/23/18 at 10:05 AM the laboratory staff confirmed that the laboratory's SOPM did not include a QA procedure to identify and correct errors in quality as they occur.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview with the laboratory staff, the laboratory did not monitor and document laboratory temperatures in order to assure accurate and reliable test results. Findings: 1. The laboratory performs dermatophyte testing at room temperature. The procedure, "Dermatophyte Testing Medium" states, "Incubate at room temperature (68F-86F) is satisfactory for growth of most dermatophytes." 2. A review of temperature records showed that there were room temperature records documented from 10/16/18 to 10/23/18. During an interview at 9:45 AM, laboratory staff stated that they were "not doing room temperatures prior to 2 weeks ago"; and 3. Record review showed that there were no refrigerator temperature records available at the time of the survey. During an interview at 9:45 AM, testing person #1 stated that they would check the refrigerator temperature every morning but did not document it. 4. During an interview on 10/23/18 at 10:30 AM, laboratory staff confirmed that refrigerator and room temperatures were not monitored and documented.

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:
Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 10/27/2016 for not recording the expiration dates of media used for dermatophyte testing. The plan of correction stated that this would be corrected. 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 February to April, 2017 showed that the sheets include the lot numbers but do not include the expiration dates of the media. 3. During an interview on 10/23/18 at 10:30 AM, the laboratory staff confirmed that expiration dates were not documented for media used for dermatophyte testing.

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 competency record review and interview with laboratory personnel, the laboratory director, acting as technical consultant (TC) failed to perform and document annual competency reviews on 3 of 3 testing personnel performing dermatophyte testing between 2016 and 2018. Findings: 1. The laboratory currently

has 3 testing personnel listed on the "Laboratory Personnel Report (CLIA) (CMS-209)." 2. A review of competency testing records showed that there were no annual competency assessments performed on 3 of 3 testing personnel performing dermatophyte testing from 2016 to 2018. Competency assessments should include: monitoring the recording and reporting of test results, review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records, or assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. 3. During an interview on 10/23/18 at 10:30 AM, laboratory personnel confirmed that the TC did not evaluate the competency of all testing personnel performing dermatophyte testing.

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:
Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 10/27/2016 for failing to ensure that testing personnel were following the laboratory's procedure for reading dermatophyte testing media at the proper time. The plan of correction stated that this would be corrected. Based on standard operating procedure manual (SOPM) and patient log record review and interview with laboratory personnel, the laboratory failed to ensure that testing personnel were following the laboratory's SOPM for reading dermatophyte testing media at the proper time. Findings: 1. The procedure "Dermatophyte Testing Medium" in the SOPM states that media should be read no later than 14 days after inoculation "due to the possibilities of false positives." 2. A review of the patient log and electronic medical record (EMR) showed that Patient #1's dermatophyte media was inoculated on 7/11/18 and should have been read and resulted on 7/25/18. The patient log showed that the patient's dermatophyte test was resulted on 8/14/18 as positive but there was no record of the result in the EMR; and 3. Patient #2's dermatophyte media was inoculated on 7/9/18 and should have been read and resulted on 7/23/18. The patient log showed that the patient's dermatophyte test was resulted on 8/15/18 as positive but the "date read" was not documented in the patient's EMR. 5. During an interview on 10/23/18 at 10:30 PM, the laboratory personnel confirmed that Patient #1 and #2's dermatophyte tests were read after 14 days incubation.