

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2111329	(X3) Date Survey Completed 03/15/2018
Name of Provider or Supplier Anne Arundel Dermatology, Pa	Street Address, City, State 1928 Alcoa Hwy, Bldg B Ste 209, Knoxville, TN	
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 review of the Laboratory's procedure manual and on interview with the Primary Histotechnician, the laboratory failed to establish procedures for Quality Assessment to include: Patient Confidentiality, Specimen Identification and Integrity, Complaint Investigations, Personnel Competency and Proficiency Testing Performance for 2017. The findings include: 1. A review of the Laboratory's procedure manual revealed no written policies to monitor, assess and correct problems identified in the laboratory. 2. Upon interview at approximately 12:00 p.m. March 15, 2018 with the Primary Histotechnician, confirmed there was no Quality Assessment Policy or monitors in place for 2017. _____</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:</p>

Based on documentation of twice a year verification for KOH (potassium hydroxide) testing for 2016 and 2017, lack of procedure for performing and reporting KOH testing and interview with the Histotechnician, the laboratory failed to have a written procedure for KOH testing for the two year period. The findings include: 1. Documentation of twice a year verification for KOH testing for 2016 and 2017. 2. Lack of procedure for performing and reporting KOH testing. 3. Interview at approximately 11:45 a.m. March 15, 2018 with the Histotechnician confirmed that KOH testing had been performed for the two year period and there was no written procedure for review.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

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.

This STANDARD is not met as evidenced by:

Based on review of MOH'S Surgery patient tracer for 10/24/17, lack of Cryostat Temperature documentation and interview with the Histotechnician, the laboratory failed to document Cryostat temperature for 10/24/17 during patient processing. The findings include: 1. Review of MOH'S Surgery patient tracer 10/24/17. 2. Lack of Cryostat Temperature documentation 10/24/17 during patient processing. 3. Interview at approximately 11:45 a.m. March 15, 2018 with the Histotechnician confirmed that Cryostat Temperature was not documented 10/24/17 during patient processing of MOH'S surgery specimen.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's weekly stainer procedure and checklist, lack of weekly cleaning documentation for 2017 and interview with the histotechnician, the laboratory failed to document weekly stainer cleanings per maintenance protocol. The findings include: 1. Review of the weekly stainer procedure and checklist states "Fridays-stainer is cleaned. All solution containers are removed and cleaned". 2. Lack of weekly Friday cleaning

documentation for 10 of 12 months in 2017. 3. Interview at approximately 11:45 a.m. March 15, 2018 with the Histotechnician confirmed the laboratory failed to document weekly stainer cleanings for 2017 per maintenance protocol.

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

_____ Based on MOH'S Surgery patient tracer 10/24/17 which lacked documentation of H&E (hematoxylin and eosin) stain quality and interview with the Histotechnician, the laboratory failed to document H&E stain quality for the day of patient testing. The findings include: 1. Review of MOH'S surgery patient tracer on 10/24/17 lacked documentation of the H&E stain quality. 2. Interview at approximately 11:45 a.m. March 15, 2018 with the Histotechnician confirmed there was no documentation of H&E stain quality on the day of patient testing 10/24/17. _____

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

_____ Based on Laboratory's "Equipment QC and Lab Director Monitoring" form, lack of director reviews for 2016 and 2017 and interview with the Primary Histotechnician, the laboratory failed to follow written policy for documenting analytic assessment reviews for the two year period. The findings include: 1. Laboratory form "Equipment QC and Lab Director Monitoring" includes monthly Lab Director reviews for: a. Cryostat b. H&E c. Stainer d. Scope 2. There were no director reviews documented for 11 of 12 months in 2016 and no director reviews documented for 2017. 3. Interview at approximately 11:45 a.m. March 15, 2018 with the primary Histotechnician confirmed the laboratory failed to follow written policy for documenting analytic assessment reviews for 2016 and 2017. _____

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

_____ Based on 4 of 4 testing personnel listed on the CMS-209 form "Laboratory Personnel Report (CLIA)" who perform KOH (potassium hydroxide) testing, lack of policy for monitoring testing personnel performing KOH testing, lack of competency documentation for 4 of 4 testing personnel performing KOH testing and interview with the Histotechnician, the laboratory director failed to ensure a policy was in place to monitor testing personnel performing KOH testing for 2016 and 2017. The findings include: 1. Four testing personnel listed on the CMS-209 form who perform KOH testing. 2. Lack of policy for monitoring testing personnel performing KOH testing. 3. Lack of competency documentation for 4 of 4 testing personnel performing KOH testing for 2016 and 2017. 4. Interview at approximately 11:45 a.m. March 15, 2018 with the Histotechnician confirmed there was no policy or competency documentation for monitoring 4 of 4 testing personnel listed on CMS-209 form who performed KOH testing during the 2 year period. _____