

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0345132	(X3) Date Survey Completed 03/10/2020
Name of Provider or Supplier Jennifer M Ridge Md	Street Address, City, State 210 N Breiel Blvd, Middletown, 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	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Clinical Manager (CM), the laboratory failed to verify the accuracy of the unregulated Mohs testing procedures performed, at least twice in 2019. All patients tested in 2019 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's 2019 Mohs test accuracy verification (TAV) documentation provided on the date of inspection revealed only one Mohs case was blindly verified for accuracy in 2019. 2. The CM confirmed only one case for Mohs TAV had been sent in 2019 for blind peer review. The interview occurred on 03/10/2020 at 10:21 AM.</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> <p>This STANDARD is not met as evidenced by: Based on record reviews and an interview with the Clinical Manager (CM), the</p>

laboratory failed to monitor and document manufacturer's requirements for room temperature and humidity. All patient histopathology testing had the potential to be affected by this deficient practice. Findings Include: 1. Review of a 1-gallon container of Poly Scientific eosin found the following manufacturer's requirements for storage: "Storage 50F to 80C" 2. Review of the manufacturer's manual for two Avantik cryostats found the following statement: "Operating conditions...+5 C up to +35C (at a max. rel. humidity of 60%)" 3. Review of the laboratory's policy and procedure manual titled "CLIA Manual" approved by the lab director did not find a room temperature and humidity policy and procedure. 4. The CM confirmed the laboratory did not follow, monitor and document the manufacturer's requirements for room temperature and humidity monitoring for the Avantik cryostats and Poly Scientific eosin storage. The interview occurred on 03/10/2020 at 12:00 PM. C; degrees Celsius F; degrees Fahrenheit

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 direct observation and an interview with the Clinical Manager (CM), the laboratory failed to ensure the tissue biopsy transport containers filled with transport media were not used beyond their expiration dates. All patient histopathology testing performed in this laboratory from 10/2019 to 03/10/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Direct observation on 03/10/2020 at 12:00 PM, found the following expired chemicals: DLCS 10% alcoholic formalin cups, lot 52548, expiration date of 10/2019 Michel 's Zeus transport media for immunofluorescent medium, lot 075550, expiration date of 03/01/2020 AAC specimen collection 10% formilan cups, lot 51167, expiration date of 10/2019 %: percent 2. The CM confirmed the tissue biopsy transport containers filled with transport media were expired and had not been removed from use. The interview occurred on 03/10/2020 at 12:00 PM.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on record review and an interview with the Clinical Manager (CM), the laboratory failed to include the name and address of the laboratory where microbiology and pathology testing procedures were performed on the final test

report. All patient test procedures performed under the specialties of pathology and microbiology had the potential to be affected by this deficient practice. Findings Include: 1. Review of one out of one of the laboratory's final test reports did not find the name and address of the laboratory where patient mycology, parasitology and histopathology procedures were performed. 2. The CM confirmed the name and address of the laboratory where patient mycology, parasitology and histopathology procedures were performed was not indicated on the final test report. The interview occurred on 03/10/2020 at 11:10 AM.