

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2073235	(X3) Date Survey Completed 11/06/2018
Name of Provider or Supplier Curcio Dermatology, Pc	Street Address, City, State 2125 Bandywood Dr, Nashville, 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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of random chart audits, Mohs Case logs, Procedure Manual, and interview with the Histotechnologist determined the laboratory failed to monitor and document the maintenance for the cryostat temperature and the automated stainer when patient samples were tested in 2017. The findings include: 1. Review of a random chart audit revealed one of four patient's surgical specimens were processed using the cryostat with no documentation of acceptable temperature and no documentation of the H & E stain maintenance for May 23, 2017. 2. Review of a random chart audit revealed one of four patient's surgical specimens were processed using the cryostat with no documentation of the temperature within acceptable limits for October 17, 2017. 3. Review of the Mohs Case log for May 23, 2017 revealed five patient specimens tested and reported and on October 17, 2017, four patient specimens were tested and reported. 4. Review of the Procedure Manual revealed "Equipment Quality control for Cryostats 1) Temperature is checked and recorded daily and documented." and "Equipment Quality Control for the Linistat Stainer 1. Stain and reagent solutions are changed daily or as needed and recorded." 5. Interview with the Histotechnologist on November 6, 2018, at 10:15 AM confirmed she had</p>

failed to document the temperature for the cryostat used to process patient specimens on May 23 and October 17, 2017, and failed to document the H & E stain maintenance for May 23, 2017.

D5601

HISTOPATHOLOGY
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of a random chart audit and interview with the Histotechnologist determined the laboratory failed to document the acceptability of the H & E control slide for May 23, 2017 when patient specimens were tested and reported. The findings include: 1. Review of the random chart audit revealed one of four patients in 2017 failed to have documentation of acceptability of the H & E control slide for May 23, 2017. 2. Interview with the Histotechnologist on November 6, 2018, at 10:20 AM confirmed she failed to document the control slide for the Laboratory Director to assess on May 23, 2017, when four patients were tested and reported.