

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0927036	(X3) Date Survey Completed 07/24/2018
Name of Provider or Supplier Pinkus Dermatopathology Laboratory	Street Address, City, State 32669 W Warren Road Suite 7, Garden City, MI	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to perform and document the room temperature and humidity readings for the dermatopathology slide tissue examination for two (July 2016 to July 2018) of two years of operation. Findings include: 1. On July 24, 2018 at 11:55 AM, record review revealed the laboratory did not perform and document room temperature and humidity readings for the Olympus DP12 and Leica DM LB microscopes used for dermatopathology tissue slide examination for two (July 2016 to July 2018) of two years of operation. 2. During the interview on July 24, 2018 at 12:15 PM, the technical supervisor as listed on the CMS-209 confirmed the room temperature and humidity readings were not performed and documented.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:

. Based on document review and interview, the laboratory failed to document the quality of the slide staining for the Hematoxylin & Eosinophil (H&E) stain and other special stains performed on the dermatopathology tissue slide examinations for ten (#1 - #10) of ten patient charts audited. Findings include: 1. On July 24, 2018 at 11:40 AM document review for ten (#1 to #10) of ten patient charts audited revealed the laboratory did not document the stain quality for the H&E or special stains that were performed on the dermatopathology tissue slide cases audited. 2. On July 24, 2018 at 11:40 AM when queried, the office staff were not able to provide the surveyor documentation to show the H&E stain quality or special stains performed for ten (#1 - #10) of ten patient audited were documented. 3. During the interview on July 24, 2018 at 12:15 PM, the technical supervisor confirmed the laboratory did not document the quality of the H&E stain or special stains.