

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0907248	(X3) Date Survey Completed 07/28/2021
Name of Provider or Supplier Pinnacle Dermatology	Street Address, City, State 833 W Lincoln Highway, Suite 205w, Schererville, IN	
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
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 observation, record review and interview, the laboratory failed to clearly define criteria for humidity for one of one staining and slide storage room. Findings include: 1) During tour of the laboratory staining and slide storage room on 7/28/21 at 11:31 am, the following equipment was observed: Leica CMS 151AS Cryostat Machine, Leica ST 4020 Slide Stainer, and Leitz Labor LUZ S Microscope were available for use. 2. Review of policy "Room Temperature and Humidity" no effective date or revision date read, "4. Humidity temperatures will vary in the climate and room temperatures. Normal ranges will vary between 15% to 65%." 3. Review of "Room Temperature/Humidity" logs indicated the following: a) Logs from "Year 2019" included acceptable humidity range of 35% to 65%. The following days were not in range per acceptable range on the log: November 19, 2019- 30% humidity; December 3, 2019- 32% humidity; December 6, 2019- 30% humidity; December 17, 2019-25% humidity. b) Logs from "Year 2020" included acceptable humidity range of 35% to 65%. The following days were not in range per the acceptable range on the log: January 14, 2020- 30% humidity; January 21, 2020- 30% humidity; February 11, 2020- 27% humidity; February 25, 2020- 30% humidity; March 28, 2020- 28% humidity; April 14, 2020- 28% humidity; May 12, 2020-28% humidity; May 26,</p>

2020- 28% humidity; June 9, 2020- 28% humidity; July 2020- 28% humidity; August 2020- 30% humidity. c) Logs from "Year 2021" included acceptable humidity range of 1% to 65% humidity. 3. In interview on 7/28/2021 at 1:02 pm, SP#1, acknowledged they did not know which humidity percentage was correct or why it was changed on the logs from 2019 and 2020 to 2021. Upon request for the manufacturer's instructions for the Cryostat and/or Slide Stainer these could not be provided to establish acceptable humidity for this equipment. 4. Annual test volume for histopathology is 350.

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 observation, record review and interview, the laboratory failed to discontinue use of two (Xylene Substitute and Vintage Bluing) of six liquids used for staining slides that had expired in one of one subspecialty of histopathology. Findings include: 1) During tour of the laboratory staining room on 7/28/21 at 11:31 am the following liquids were observed to have expired: a) One container of XS-3 Xylene Substitute, expired 6/14/2019, Lot 7400-1. There were no additional containers of Xylene Substitute found. b) Two containers of Vintage Bluing SL102, expired 7/1/2021, both were Lot 068134 and were open for use. The cabinet held another container of Vintage Bluing, but it was not open. 2. Review of policy "Automatic Staining Procedure", no effective or revision date, indicated both "Bluing (Vintage)" and "Xylene Substitute" were required for staining slides. "The maintenance is as follows: Change first alcohol (fixative) and Bluing (daily)... The slides are then dropped into (by the chain) the larger container of xylene substitute. The slides remain in the xylene substitute until alcohol residue is removed. ***Xylene substitute is replaced monthly or as needed." 3. Review of medical records indicated eight of eight reviewed has slides created after the Xylene Substitute had expired. Patient Date of test PT#1 2/23/2021 PT#2 12/31/2019 PT#3 9/8/2020 PT#4 4/14/2020 PT#5 8/9/2019 PT#6 3/24/2020 PT#7 10/13/2020 PT#8 3/9/2021 4. Review of "Room Temperature /Humidity" logs from "Year 2021" indicated there were two days where slides were created in July 2021 after the Vintage Bluing liquid had expired: July 13, 2021, and July 27, 2021. 5. During interview on 7/28/2021 at 11:31 am, SP #1 confirmed the one container of Xylene Substitute had expired on 6/14/2019 and no other containers were available. SP#1 further confirmed the two containers of Vintage Bluing had expired on 7/1/2021. 6. Annual test volume for histopathology is 350.