

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D1013778	<b>(X3) Date Survey Completed</b> 02/15/2018
<b>Name of Provider or Supplier</b> Cumberland Dermatology, Pc	<b>Street Address, City, State</b> 29 Taylor Ave, Suite 101, Crossville, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the PT records in 2016-17 and an interview with the lead histotech determined the laboratory director failed to ensure that all PT attestation statements are signed during 2017. The findings include: 1. Review of the 2017 events 1st-3rd PT records for the clinical microscopy photographs for the specialties of mycology and parasitology revealed the laboratory director did not sign the attestation statements for testing persons during the 1st and 3rd events of 2017. 2. Interview with the lead histotech on February 15, 2018, at approximately 10:50 AM confirmed that the director failed to attest/sign attestation statements for the 2017 PT events 1st-3rd.</p>
<b>D5413</b>	<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</p>

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 a review of the equipment quality control -cryostat policy, maintenance temperature logs for 2016-17 and an interview with the lead histotech, the laboratory failed to take corrective actions for high temperature recordings on the cryostat from February 1st through June 20th, 2016. Findings include: 1. Review of laboratory equipment quality control -cryostat policy showed the temperature range is -20°C to -30°C. 2. Review of the cryostat temperature logs for days of surgery revealed high temperatures without corrective actions from February 1st through June 20th, 2016. 3. In an interview, on February 15, 2018, at approximately 9:50am, the lead histotech confirmed the laboratory failed to take corrective actions for high temperatures for the cryostat from February 1st through June 20th, 2016.

**D5609**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on a 2016-18 review of the laboratory histology stain logs, patient test reports of five histopathology patient records, and an interview with the lead histotech, the laboratory failed to document the expiration dates for stains (hematoxylin and eosin-H&E). Findings include: 1. A review of histology stain logs for 5 of 5 patient test reports audited from 2016-18 confirmed the expiration dates missing for H&E stains for the dates of service for 2016-2018. 2. In an interview, on February 15, 2018, at 11:15am, the lead histotech confirmed the histology stain logs were missing the expiration dates for H&E stains for 5 of 5 audited patient test reports for 2016-18.