

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2005885	<b>(X3) Date Survey Completed</b>  08/25/2022
<b>Name of Provider or Supplier</b>  Cylburn E Soden, Md, Pa	<b>Street Address, City, State</b>  13920 Baltimore Avenue, Laurel, MD	
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>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 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 review and interview, the laboratory did not define the operation temperature of the cryostat, used to prepare patient specimens for microscopic examination. Findings: 1. The operational range for the cryostat was - 20C to - 35 C in the standard operating procedure and - 30 C to - 27 C on the daily worksheet, these two ranges do not match; 2. This was confirmed with laboratory staff at exit on the afternoon of the day of survey</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and exit interview, the laboratory did not document the manufacturer name, lot number and expiration date of the H&amp;E staining reagents and</p>

stains used to process patient specimens (if applicable) to ensure they were not used past expiration. Findings: 1. The laboratory did not record the manufacturer name, lot number and expiration dates of reagents and stains used for the H&E stain (if provided by the manufacturer); 2. This was confirmed with laboratory staff at exit on the afternoon of the day of survey.