

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0946570	<b>(X3) Date Survey Completed</b>  02/26/2019
<b>Name of Provider or Supplier</b>  Eastern Shore Pathology	<b>Street Address, City, State</b>  750 Morphy Ave, Fairhope, AL	
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 an observation, a record review of the 2017-2019 environmental logs, a review of environmental requirements for the Leica CM1850 Cryostat and an interview with the Histology Supervisor, the surveyor determined the laboratory failed to correctly specify acceptable ranges (as defined by the manufacturer), and ensure staff were trained in the correct usage of the electronic thermometer / hygrometer. The findings include: 1. A review of the internet User's Manual for the Leica CM1850 Cryostat under section "4.1 Site Requirements" revealed, the instrument should be utilized in a maximum room temperature of 35 degrees C (Celsius), and the air humidity should not exceed 60% (percent). 2. A review of the 2017-2019 laboratory environmental records revealed the following: A) 2017 Environmental Logs (Room) a) Acceptable room temperature documented as 20-50 degrees C with the minimum-34, and the maximum-36 for the entire year b) Acceptable room humidity documented as 20-50% with the minimum-34, and the maximum-36 for the entire year B) January 2018 thru February 2019 Environmental Logs (Room) a) Acceptable room temperature documented as 20-30 degrees C with the minimum-28, and the maximum-30 for the 14-month period b) Acceptable room humidity documented as 20-50% with the minimum-34, and the maximum-36 for the 14-month period C) January 2017 thru February 2019 refrigerator temperatures with the minimum-4, and the maximum-6</p>

without variation for the 26-month period 3. During an interview on 2/26/2019 at 1:50 PM, the surveyor reviewed the Leica CM1850 Cryostat environmental requirements with the Histology Supervisor, who confirmed the laboratory had not been using the correct parameters. 4. As the interview continued, the surveyor asked to review the operation of the electronic thermometer / hygrometer. The laboratory used a Fisher Scientific digital device which documented the minimum and maximum humidity and temperature with a small reset button on the back. The surveyor reset the device, and observed a current temperature of 23 degrees C, and humidity of 42%. Noting the lack of variation in the 2017-2019 environmental records, the surveyor then asked the Histology Supervisor if the staff member who recorded the information had been trained in the correct usage of the device. The Supervisor confirmed additional training of the employee was needed to ensure she documented the correct temperatures and humidity for each 24-hour period, and then reset the device each day. Thus the above noted findings were confirmed. SURVEYOR ID #32558  
Licensure and Certification Surveyor