

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0956156	<b>(X3) Date Survey Completed</b>  06/27/2018
<b>Name of Provider or Supplier</b>  Sacred Heart Health System, Inc	<b>Street Address, City, State</b>  4591 Santa Villa Dr, Pace, FL	
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, it was determined that the laboratory did not document room temperature to assure optimal storage temperature for certain reagents for 2 years from 2016 - 2018. Findings included: Review of the manufacturer's instructions indicated that the Uricult ( media ) should be stored at a temperature between 7-25 degrees Celsius. There was no temperature log available for documenting the temperature of the laboratory room. Interview on 6/27/18 at 11:00 AM, testing person # 8 confirmed that the temperature of the laboratory room was not checked and documented.</p>