

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D1043251	<b>(X3) Date Survey Completed</b>  11/08/2018
<b>Name of Provider or Supplier</b>  Asloyan Medical Pc	<b>Street Address, City, State</b>  2626 East 14 Street, Suite 104, Brooklyn, NY	
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 surveyor's review of laboratory's temperature policy, review of I and II refrigerator temperature logs and direct observation of I &amp; II refrigerators and an interview with the technical consultant, the laboratory failed to take corrective action when it failed to have a thermometer for the II refrigerator and did not record refrigerator I temperature used to store the reagents, control &amp; calibration material for the Horiba ABX Pentra 400 chemistry analyzer and Beckman Access 2 endocrinology analyzer. FINDINGS: 1. The technical consultant confirmed on November 8, 2018 at 11:30 AM, that the laboratory failed to have a thermometer for the II refrigerator used to store the reagents, control &amp; calibration material for the Horiba ABX Pentra 400 chemistry analyzer and did not record refrigerator I temperatures from January 2, 2018 through survey date . a. The Horiba manufacturer requires a storage temperature of 2-8C or 35 to 45 F. b. The refrigerator was installed in the month of October 2018. No records of refrigerator II temperatures were available for review from October 2018 through survey date. 2. The Beckman manufacturer requires a storage temperature of 2-8C or 35 to 45 F. a. No records of refrigerator I temperatures were available for review from January 2, 2018 through survey date for refrigerator I used to store the Beckman Access 2 October 2018 through survey date.</p>