

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2079846	(X3) Date Survey Completed 07/30/2019
Name of Provider or Supplier Khoury Medical Care Pc	Street Address, City, State 1184 Brighton Beach Avenue, Brooklyn, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5413	<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 the laboratory's temperature logs and an interview with the technical consultant, the laboratory failed to monitor the room and refrigerator /freezer temperatures for the calendar year 2018 through survey date. FINDINGS: 1. The technical consultant confirmed on July 30, 2019 at approximately 2:30 PM, that the laboratory testing person did not record the exact temperatures from the thermometers but used a check mark instead for the calendar years 2018 through survey date. 2. The manufacturers for the following analyzers: Horiba Pentra 400, Abbott Cell-Dyn 1700, Beckman Access 2, BD Viper LT, Bio-rad PR4100 and Alere Affirm VPN require the temperatures as follows: room 15-30C or 68-77 F; refrigerator 2-8C or 35-45F and freezer at -20C. a. The laboratory stores test kits, reagents at room temperature, control and calibration material, patient specimens, Proficiency testing samples in the refrigerator and/or freezer. 3. The surveyor could not determine if the temperatures were within the required ranges for the calendar year 2018 through survey date. a. The laboratory's temperature logs did have the above ranges recorded on the top of the log sheets b. The testing person did not record the exact temperatures from the thermometers but used a check mark instead. 4. Approximately 250 patient samples were stored in the refrigerator and tested during the above time-period.</p>