| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 21D0673360 | 05/17/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Levindale Hebrew Geriatric Center And Hospital | 2434 W Belvedere Avenue, Baltimore, MD | |

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** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with the point-of-care (POC) staff, the laboratory did not monitor the temperature of the room where the reagent packets for the EPOC (blood gas analyzer) were stored prior to use. Findings: 1. The laboratory records for 2017 through May 2019 were reviewed. These records did not include documentation showing that the room temperature where the reagent packets were stored for a few weeks prior to testing was being monitored on a daily basis. 2. According to the POC staff the reagent packets for the EPOC are store in a room in the hospital across the street until needed. This room temperature is monitored on a daily basis. Once the reagent packets are transferred to the licensed off-site testing location the room where they are being stored was not being monitored until 02/28 /2019. 3. During the validation survey on 05/17/2019 at 11:30 AM the POC staff confirmed that the room temperature of the reagent storage room at the licensed off-site location was not being monitored prior to 02/20/2019 until the new procedure was approved on 02/28/2019. |