

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D2065372	<b>(X3) Date Survey Completed</b>  09/18/2023
<b>Name of Provider or Supplier</b>  Healthland Housecall Services	<b>Street Address, City, State</b>  100 E Big Beaver Road Suite 900, Troy, MI	
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 with the Technical Consultant, the laboratory failed to document temperature monitoring for its refrigerator each day of patient testing for 1 (July 2022) of 16 months of testing reviewed. Findings include: 1. A record review of the laboratory's "Temp Log" revealed for 1 (July 2022) of 16 months reviewed the laboratory did not take temperatures on two days of patient testing as follows: a. July 1, 2022 - 16 patients run on the hematology analyzer. b. July 18, 2022 - 12 patients run on the hematology analyzer. 2. An interview on 9/18/2023 at 10:30 am, the Technical Consultant confirmed no July 2022 refrigerator temperatures were taken and documented.</p>