

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1069494	(X3) Date Survey Completed 09/09/2021
Name of Provider or Supplier Uinta Basin Medical Center Manila Clinic	Street Address, City, State 100 West 96 North, Manila, UT	
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 record review, direct observation, and interview with testing personnel 1 (TP1), room temperature and humidity were not monitored. Refrigerator temperature was not monitored. The laboratory performs approximately 15 Complete Blood Counts (CBC) tests annually. Findings include: 1. Record review did not include daily room temperature and humidity for the room where instrumentation was located. Refrigerator temperature was not recorded daily. 2. Refrigerator thermometer calibration sticker stated the thermometer expired 04/29/2015 and the thermometer probe expired 11/11/2019. 3. CELL-DYN controls and calibrators are stored at 2- 8 C. 4. In an interview on 09/09/2021 at approximately 12:50 PM, TP1 confirmed that the thermometer and probe had not been calibrated. 5. The TP1 confirmed that the daily temperature check is only performed by one clinic staff. Testing is performed regardless if temperature checks are completed and that staff is working that day. 6. No thermometer or hygrometer was present in the room with the laboratory during observation. 7. The CELL-DYN Emerald manufacturer requires the instrument to operate at temperature range of 18 - 32 C and a maximum relative humidity of 80%. 8. In an interview on 9/09/2021 at approximately 1:15 PM, testing personnel 1 confirmed that room temperature and humidity was not monitored.</p>