

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2256548	(X3) Date Survey Completed 08/22/2022
Name of Provider or Supplier Acies Molecular Lab, Llc	Street Address, City, State 4000 Discovery Ct, New Albany, IN	
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 observation, record review and interview, the laboratory failed to monitor the temperature of one of one -80 freezer which held Covid-19 control materials from 8/1/2022 -8/21/2022. Findings included: 1. During a tour of the molecular area on 8/22 /2022 at 11:00 AM, a freezer was observed with a temperature of -86 Celsius (C). The freezer contained Taqpath COVID-19 Control pack with an expiration of 1/5/2023. 2. Review of August 2022 "Maintenance Checklist": "Daily Freezer Temp#3" revealed no dates were recorded for the freezer #3 until 8/22/2022 with a temperature of -86 C. 3. During interviews on 8/22/2022 at 3:13 pm, SP#1 (General Supervisor), SP#2 (Director of Operations), and SP#3 (Owner) confirmed COVID-19 and respiratory panel testing began on 7/6/2022 and they did not have documentation of monitoring of freezer temperature for August 2022.</p>