

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2277604	(X3) Date Survey Completed 12/28/2023
Name of Provider or Supplier Innosign, Inc	Street Address, City, State 5155 Financial Way, Suite 17, Mason, OH	
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 direct observation, record review and an interview with the General Supervisor (GS), the laboratory failed to monitor and document refrigerator and freezer temperatures for proper storage of reagents. This deficient practice had the potential to affect 1000 out of 1000 patients tested under the specialty of Clinical Cytogenetics from 09/08/2023 through 12/28/2023. Findings include: 1. Direct observation of the Hisense refrigerator and freezer units used to store reagents did not find any thermometers for one out of one refrigerator and two out of two freezers. 2. The GS checked the "Temp Stick" (wifi enabled) automatic uploaded temperature recording sheet and discovered no temperatures had been recorded since September 8, 2023. 3. A review of the manufacturer's package inserts for each reagent stored in the unmonitored refrigerator and freezers found the following storage requirements: Reagent Storage Qiagen Rneasy 2 - 8C Invitrogen qRT 2 - 8C InnoSIGN G7 -20C InnoSIGN Gene Plate -20C ThermoFisher PCR Kit -20C ThermoFisher TaqMan -20C 4. On the date of inspection at 12:10 PM, the GS confirmed the Hisense refrigerator and freezers were not monitored for temperatures, and was unable to provide temperature records for the Hisense refrigerator and freezer units where reagents were stored. C; degrees Celsius</p>