

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2016117	(X3) Date Survey Completed 04/05/2023
Name of Provider or Supplier Crescent City Surgical Centre Diagnostics, Llc	Street Address, City, State 3016 Galleria Drive, Metairie, LA	
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: A Follow-up survey was performed at Crescent City Surgical Centre, CLIA # 19D2016117 on April 4, 2023 through April 5, 2023. Based on observation by surveyors, review of the laboratory's temperature logs, and interview with laboratory personnel, the laboratory failed to ensure supplies were stored per the manufacturer's requirements for forty-one (41) of sixty-seven (67) days reviewed. Findings: 1. On April 4, 2023 at 9:45 a.m. during the laboratory tour, surveyor observed one (1) box of gram stain quality control slides Lot #004732 with storage requirements of 20-35 degrees Celsius in the storage room. 2. Review of the laboratory's temperature logs revealed the laboratory defined the storage room's acceptable temperature limits as 15-25 degrees Celsius. 3. Further review of the laboratory's temperature logs revealed the laboratory documented temperatures below the manufacturer's requirements of 20-25 degrees Celsius on the following days: January 2, 2023 - 18.1 degrees Celsius January 3, 2023 - 18.2 degrees Celsius January 4, 2023 - 19.9 degrees Celsius January 10, 2023 - 18.1 degrees Celsius January 11, 2023 - 18.7 degrees Celsius January 12, 2023 - 18.6 degrees Celsius January 16, 2023 - 18.3 degrees Celsius January 17, 2023 - 18.7 degrees Celsius January 18, 2023 - 17.9 degrees Celsius January 19, 2023 - 18.7 degrees Celsius January 30, 2023 - 17.8 degrees Celsius January 31, 2023 - 18.9 degrees Celsius February 1, 2023 - 18.1 degrees Celsius February 3, 2023 - 18.6</p>

degrees Celsius February 6, 2023 - 19.2 degrees Celsius February 7, 2023 - 17.6
degrees Celsius February 9, 2023 - 19.3 degrees Celsius February 14, 2023 - 17.7
degrees Celsius February 15, 2023 - 17.7 degrees Celsius February 16, 2023 - 17.9
degrees Celsius February 20, 2023 - 17.7 degrees Celsius February 21, 2023 - 17.9
degrees Celsius February 22, 2023 - 18.1 degrees Celsius February 24, 2023 - 18.3
degrees Celsius February 27, 2023 - 17.7 degrees Celsius February 28, 2023 - 17.8
degrees Celsius March 1, 2023 - 18.1 degrees Celsius March 2, 2023 - 19.3 degrees
Celsius March 3, 2023 - 18.6 degrees Celsius March 6, 2023 - 18.4 degrees Celsius
March 7, 2023 - 17.0 degrees Celsius March 8, 2023 - 16.9 degrees Celsius March 9,
2023 - 17.8 degrees Celsius March 10, 2023 - 17.0 degrees Celsius March 13, 2023 -
17.3 degrees Celsius March 20, 2023 - 19.5 degrees Celsius March 21, 2023 - 18.6
degrees Celsius March 24, 2023 - 19.8 degrees Celsius March 27, 2023 - 18.6 degrees
Celsius March 28, 2023 - 19.2 degrees Celsius March 31, 2023 - 19.2 degrees Celsius
4. In interview on April 4, 2023 at 10:22 a.m., the Technical Consultant stated the
item was not in use and was purchased for possible future testing. She confirmed the
item was not stored at the manufacturer's required temperature.