

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2101760	(X3) Date Survey Completed 12/16/2025
Name of Provider or Supplier Gulf Coast Interventional Spine & Joint Specialist	Street Address, City, State 1557 Spring Hill Ave, Mobile, AL	
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>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 reviews of the freezer temperature records, the Quidel Triage Drug Screen Quality Control (QC) package inserts and an interview with Laboratory Director (LD), the laboratory failed to ensure QC materials were stored within the manufacturer's acceptable limits. Freezer temperatures were warmer than the acceptable ranges from the date of the last survey, 06-08-2023 to the date of the current survey, 12-16-2025. The findings include: 1. A review of the temperature records revealed the freezer temperature where the QC materials were stored from 2023-2025 was warmer than the manufacturer's acceptable limits of at least minus 20 degrees Celsius. 2. A review of the Quidel Triage Drug Screen QC package insert for storage and handling requirements revealed, "Store frozen at minus 20 degrees Celsius or colder..." 3. During the exit conference on March 28th, 2023, at 1:30 PM, LD confirmed the above findings.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and</p>

other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observations during the laboratory tour, a review of the manufacturer's guidelines for optimum use of the Quidel Triage test devices and an interview with the Laboratory Director (LD), the laboratory staff failed to record the new expiration for Triage Urine Drug Screen (UDS) test devices after they were transferred from the refrigerator to room temperature storage. The surveyor noted one of the 25 test devices had been utilized for testing. The findings include: 1. During the laboratory tour on 12-16-2025 at approximately 8:22 AM, the surveyor observed an opened box of room temperature UDS test devices without any dates written on the box or on the individual pouch. The testing personnel failed to record the new expiration date for test devices transferred from refrigerator to room temperature storage. 2. A review of the manufacturer's guidelines on the Top 10 Tips for the Quidel Triage UDS test devices revealed the following, "Once removed from refrigeration, the pouched Test Device is stable up at room temperature for up to 14 days ..." 3. LD confirmed the above findings during the exit conference on 12-16-2025 at 1:30 PM.