

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2063340	(X3) Date Survey Completed 03/01/2022
Name of Provider or Supplier Gulf Coast Pain Consultants Pllc	Street Address, City, State 4901 Marketplace Rd, Pensacola, FL	
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
D0000	A recertification survey was conducted on 2/17/2022 at Gulf Coast Pain Consultants, PLLC. The survey continued through 3/01/2022 to gather additional documentation. Gulf Coast Pain Consultants, PLLC, clinical laboratory was not in compliance with 42 CFR 493, Requirements for Laboratories.
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with lab staff, the laboratory failed to document corrective actions for the Mini-Freezer temperatures that were out of acceptable range, during the month of June, 2021. Findings included: On the "Samples Fridge/Samples Freezer//Heat Block" log sheet the acceptable temperature limits were -18 Celsius (C) to -20 Celsius (C) for the Mini-Freezer. No corrective actions were documented for: June 14, 2021 - temperature documented -17 (C) June 18, 2021 - temperature documented -17 (C) June 21, 2021 - temperature documented -17 (C) During interview with all lab staff, it was confirmed that no corrective actions were documented for the dates provided.</p>