

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2056631	(X3) Date Survey Completed 03/30/2021
Name of Provider or Supplier Treasure Coast Pathology Lab Llc	Street Address, City, State 275 18th St Ste 101, Vero Beach, 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 March 30, 2021. Treasure Coast Pathology Lab, LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document corrective actions when the refrigerator was out of range in the laboratory from 07/10/2019 to 03/30/2021. Findings: Review of the Schiff Reagent stored in the laboratory refrigerator showed a storage requirement of between 33-46 degrees Fahrenheit which equals 0.56-7.78 degrees Celsius (C). Review of the daily temperature log for the refrigerator showed the temperature was below -1 degrees C from 07/10/2019 to 03/30/2021. No corrective action was noted on the temperature log. The Clinical Laboratory Improvement Amendments (CLIA) Applications for Certification, signed and dated by the Laboratory Director on 03/09/2021, noted the laboratory has an estimated test volume of 4,200 tests per year. During an interview on 03/30/21 at 2:18 PM, the Testing Personnel A stated the temperature for the refrigerator was too cold.</p>