

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0965332	(X3) Date Survey Completed 11/16/2023
Name of Provider or Supplier Bio-Tech Clinical Laboratories Inc	Street Address, City, State 9000 Nw 15th St Unit 1, Doral, 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
D5300	<p>PREANALYTIC SYSTEMS CFR(s): 493.1240</p> <p>Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on observation, review of the procedure manual and test results, and interview, the laboratory failed to correct identified problems in the Preanalytic Systems. Findings included: The laboratory failed to follow their written policy for specimen integrity for five of 46 samples observed on 11/16/2023. This deficiency was not corrected from the recertification survey. Refer to D5311</p>