

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0645095	(X3) Date Survey Completed 03/30/2022
Name of Provider or Supplier Florida Dept Of Health Bureau Of Public Health Lab	Street Address, City, State 1217 N Pearl St, Jacksonville, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on direct observations, review of manufacturer's instructions, and interview, the laboratory failed to follow manufacturer's instructions for the Aptima Combo 2 Assay (panther system) for cross contamination during the March 2022 revisit as evidenced by: 1. In review of the manufacturer's instructions for Aptima Combo 2 Assay (panther system) pg 5 General information states, "Avoid-contamination during the specimen handling steps. Specimens can contain extremely high level of organisms. Ensure that specimen containers do not contact one another, and discard used materials without passing over open containers..." 2. In direct observation on 3-29-2022 @1005, the following patients were observed together touching each other in a plastic biohazard bag: a. Patient #3610130932 (urine tube) b. Patient #3610130935 (urine tube) c. Patient #31610130929 (urine tube) 3. In direct observation 3-29-2022 @1007, there were 45 urine specimens from Orange County that were stuffed touching each other in one metal cylinder shipping container shipped FedEx 4. In direct observation on 3-29-2022 @1009, laboratory personnel were opening the packaged metal cylinder shipping containers, and placed hundreds aptima urine tubes in a white bucket (the urine tubes were touching each other) before going to the department for testing. 4.. In interview with the Quality Control officer on 3-29-2022 @1010, stated that she were not aware that the Aptima's could not touch each as per the manufacturer's instructions.</p>