

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0997995	(X3) Date Survey Completed 08/24/2021
Name of Provider or Supplier Jhu Bloomberg School Of Public Health	Street Address, City, State 615 N Wolfe St Room E1200tr3 Bldg, Baltimore, MD	
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 review of the manufacturer's product inserts, final patient report and interview with the technical supervisor, the laboratory failed to follow the manufacturer's instructions for establishing their own normal reference range for the patient population they are testing. Findings: 1. The manufacturer's product inserts for BD Tritest CD3/CD4/CD45 and BD Tritest CD3/CD8/CD45 were reviewed. Both product inserts are dated 5/2014. Section 9. Limitations for both inserts state: Laboratories must establish their own normal reference ranges for the BD Tritest CD3 /CD4/CD45 and CD3/CD8/CD45 reagent parameters that can be affected by gender of patient, age of patient, and preparative technique ... Reference ranges provided are for information only. 2. The final report provided by the laboratory for T-HELPER Cells, Number and Percent and T-SUPPRESSOR Cells, Number and Percent provided a value but did not include a reference range for the evaluation of each test result. 3. During the survey on 08/24/2021 at 11:00 PM the, technical supervisor confirmed that the normal patient reference range was not available on the final report.</p>