Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 21D2041831	**(X3) Date Survey Completed** 05/30/2019
Name of Provider or Supplier Central Booking & Intake Ctr, Mdh Stat Laboratory	**Street Address, City, State** 300 East Madison Street, Room 2s69, 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**
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish performance specifications for Sure-Vue RPR (Rapid Plasma Reagin) when a modification was made to the manufacturer's stated interval between patient specimen collection and testing. Findings include: 1. Review of the manufacturer's instructions, Section 9.3 revealed "...serum samples should be tested within 5 days of collection..." 2. The laboratory's procedure, CBIF v. 2.4, stated in the "Specimen" section, 3., "...serum samples should be tested within 7 days of collection..." 3. Interview with the technical consultant on 5/30/2019 at approximately 11:30 am confirmed that the laboratory's procedure did not follow the manufacturer's instructions for testing of specimens after collection and that the laboratory did not perform establishment studies.