Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0319979	06/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Brookhaven Urology	425 Highway 51 North, Brookhaven, MS	

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
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's acceptable ranges for BioRad Liquichek Immunoassay Plus controls, quality control (QC) records for the Beckman Coulter Access 2 immunoassay system from 11/1/21 through 5/27/22, and patient test results, at least one of two levels of control failed to meet the manufacturer's criteria for acceptability for four days during these seven months, when a total of forty-one patient prostate specific antigen (PSA) tests were performed and reported. Findings include: Review of manufacturer's acceptable ranges for BioRad Liquichek Immunoassay Plus controls - Level 1, Lot #35271, and Level 3, Lot #35273, QC records for the Beckman Coulter Access 2 immunoassay system from 11/1/21 through 5/27/22, and patient test results revealed on the following days Level 3, of the two levels of control, was outside the manufacturer's acceptable range when the patient PSA tests listed below were performed and reported: 1/25/22 - Patients #49551, #6102, #42014, #7363, #45809, #41380, #23463, #46689. 1/28/22 - Patients #54520, #54130, #53392, #52731, #42391. 2/2/22 - Patients #30363, #54426, #28283, #54526, #26025, #49487, #42031, #50525, #9846, #20474, #53071, #43141, #353, #51865, #9484. 2/4/22 - Patients #50495, #50439, #51538, #7251, #54497, #47524, #25312, #52157, #51336, #41294, #52525, #40963, #43524. THIS IS A REPEAT DEFICIENCY.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5)

	Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on review of manufacturer's acceptable ranges for BioRad Liquichek Immunoassay Plus controls, quality control (QC) records for the Beckman Coulter Access 2 immunoassay system from 11/1/21 through 5/27/22, and patient test results, the testing personnel responsible for moderate-complexity PSA testing failed to identify problems that could adversely affect test performance and failed to correct the problem or immediately notify the technical consultant or laboratory director when one of two levels of control failed to meet acceptable criteria for four days, when a total of forty-one patient PSA tests were performed and reported. Refer to D5481 (Failure to ensure controls were acceptable before reporting patient test results).