Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0319979	03/07/2018
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records since the last survey on 4-27-16, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and personnel records, proficiency testing was not rotated among the four testing personnel, who performed patient prostate specific antigen (PSA) testing during this time frame. Findings include: Review of the CMS 209 personnel form and PT records since the last survey on 4-27-16 revealed Testing Personnel #1, listed on the CMS 209 personnel form, performed four of the five PT events since 4-27-16, and Testing Personnel #2 performed one of the five PT events. There was no documentation that Testing Personnel # 3 and #4 participated in performance of proficiency testing since 4-27-16. Review of personnel records since 4-27-16 revealed Testing Personnel #3 and #4 performed patient PSA testing during this time frame.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on the number of deficiencies cited for analytic systems, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 or monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. Refer to D5411 (Failure to follow manufacturer's instructions for frozen storage of controls). Refer to D5417 (Failure to ensure controls were not used past the open-vial stability date). Refer to D5431 (Failure to ensure weekly System Checks were within the manufacturer's limits before patient testing was performed). Refer to D5481 (Failure to ensure results of quality control testing were acceptable before reporting patient test results).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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. This STANDARD is not met as evidenced by: Based on observation of frozen unopened vials of BioRad Liquichek Immunoassay Plus Controls stored in the freezer compartment of the laboratory refrigerator on 3-7-18 at 10:05 a.m., the manufacturer's instructions, and the freezer temperature logs since the BioRad Liquichek Immunoassay Plus Controls were put in use for PSA testing on 4-11-17, the laboratory failed to follow manufacturer's instructions for frozen storage of unopened vials of BioRad Liquichek Immunoassay Plus Controls. Findings include: Manufacturer's instructions for BioRad Liquichek Immunoassay Plus Controls state, "This product will be stable until the expiration date when stored unopened at minus 20 degrees to minus 70 degrees Celsius." Ten unopened vials of BioRad Liquichek Immunoassay Plus Controls Lot #40951, eleven vials of Lot #40953, twelve vials of Lot #40961, and twelve vials of Lot #40963 were observed stored in the freezer compartment of the laboratory refrigerator on 3-7-18 at 10:05 a.m. Review of temperature logs for the freezer compartment of the laboratory refrigerator since the BioRad Liquichek Immunoassay Plus Controls were put in use for PSA testing on 4-11-17 revealed the freezer compartment daily temperatures fell outside the manufacturer's acceptable range for frozen storage every day the temperature was recorded from 4-11-17 through 3-7-18.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of opened vials of BioRad Liquichek Immunoassay Plus Controls, currently in use for prostate specific antigen (PSA) testing, in the laboratory refrigerator on 3-7-18 at 10:00 a.m. and review of the manufacturer's instructions, the

	laboratory failed to document an open date to ensure the controls were not used past the manufacturer's open-vial stability of fourteen days. Findings include: Manufacturer's instructions for BioRad Liquichek Immunoassay Plus Controls state, "Once thawed, opened, and stored tightly capped at 2 to 8 degrees Celsius, this product will be stable for 14 days." Observation of opened vials of BioRad Liquichek Immunoassay Plus Controls, currently in use for PSA testing (Level 1 - Lot #40951 and Level 3 - Lot #40953), in the laboratory refrigerator on 3-7-18 at 10:00 a.m. revealed no open date to determine if the vials of control were used past the stability date.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of weekly System Check Reports from 10-25-17 through 3-7-18 for the Beckman Coulter Access 2 Immunoassay System, used for patient prostate specific antigen (PSA) testing, Access 2 Immunoassay System Instructions for Use, patient test results, and lack of documentation of corrective action for failed System Checks, the laboratory failed to ensure weekly System Checks were within the manufacturer's established limits before patient testing was performed for six weeks during this time frame when a total of 380 patient PSA test results were reported. Findings include: The Beckman Coulter Access 2 Immunoassay System Instructions for Use state, "The System Check routine is typically run as part of weekly maintenance to verify that the Access 2 system is operating properly." Review of weekly System Check Reports from 10-25-17 through 3-7-18 for the Beckman Coulter Access 2 Immunoassay System and patient test results revealed the weekly System Check failed on the following weeks when patient PSA testing was performed and results reported: 11-1-17 through 11-7-17--69 patient PSA results reported. 11-8-17 through 11-14-17--53 patient PSA results reported. 1-31-18 through 2-6-18--83 patient PSA results reported. 2-14-18 through 3-6-18--175 patient PSA results reported. There was no documentation of corrective action for the failed System Checks available for review on the day of the survey, 3-7-18.
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 11-1-17 through 1-31-18, and patient test results, the Level 1 control result, of two levels of control, failed to meet the manufacturer's criteria for acceptability on 12-5-17, when a total of seven patient test results were

	reported. Findings include: Review of QC records for the Beckman Coulter Access 2 immunoassay system from 11-1-17 through 1-31-18 and patient test results revealed Level 1, of two levels of control material, failed to meet the manufacturer's criteria for acceptability on 12-5-17, when the following patient PSA results were reported: Patient #20870, #3948, #43890, #44249, #2309, #46655, and #24028.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the number of deficiencies cited for analytic systems, technical consultant responsibilities, and laboratory director responsibilities, the laboratory director failed to provide overall management and direction of the laboratory in accordance with 493.1407 of this subpart. Refer to D5400 (Condition of Analytic Systems). Refer to D6033 (Condition of Technical Consultant). Refer to D6013 (Failure to ensure verification of performance specifications was adequate). Refer to D6029 (Failure to ensure testing personnel received appropriate training). Refer to D6031 (Failure to ensure an approved procedure manual was available to testing personnel).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the verification of performance specifications for the Beckman Coulter Access 2 Immunoassay System performed at installation in April 2017 and lack of documentation of review of these records, the laboratory director failed to ensure that the verification procedures used were adequate to determine the accuracy, precision, and linearity of the Access 2 Immunoassay System, which was put in use for patient prostate specific antigen (PSA) testing on 4-11-17. Findings include: Review of the verification of performance specifications for the Beckman Coulter Access 2 Immunoassay System revealed a linearity study and a method comparison with the Abbott Architect Immunoassay System were performed on 4-4-17, and a precision study was performed on 4-6-17. However, there was no documentation of review of these records by the laboratory director to ensure these verification procedures were adequate to determine the accuracy, precision, and linearity of the Beckman Coulter Access 2 Immunoassay System before the system was put in use for patient PSA testing on 4-11-17.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records, the CMS 209 personnel form, installation records for the Beckman Coulter Access 2 immunoassay system, and lack of documentation of training, the laboratory director failed to ensure the four testing personnel, listed on the CMS 209 personnel form, received appropriate training for performing prostate specific antigen (PSA) testing with the Beckman Coulter Access 2 immunoassay system, prior to testing patient specimens. Findings include: Review of installation records for the Beckman Coulter Access 2 immunoassay system revealed the system was put in use for patient PSA testing on 4-11-17. Review of installation records for the Access 2 immunoassay system and personnel records for the testing personnel listed on the CMS 209 personnel form revealed no documentation of training on the Access 2 immunoassay system for the four individuals responsible for PSA testing, prior to testing patient specimens. Refer to D5411 (Failure to follow manufacturer's instructions for frozen storage of controls). Refer to D5417 (Failure to ensure controls were not used past the open-vial stability date). Refer to D5431 (Failure to ensure weekly System Checks were within the manufacturer's limits before patient testing was performed). Refer to D5481 (Failure to ensure results of quality control testing were acceptable before reporting patient test results).
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the Instructions for Use manual for the Beckman Coulter Access 2 immunoassay system, put in use for patient PSA testing on 4-11-17, and lack of documentation of review, the laboratory director failed to approve the manufacturer's Instructions for Use manual for use by testing personnel as a procedure manual for PSA testing.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409

	The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on the number of deficiencies for technical consultant responsibilities and analytic systems, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Refer to D5400 (Condition of analytic systems). Refer to D6044 (Failure to ensure corrective actions have been taken and test system is functioning properly before reporting patient results). Refer to D6048 (Failure to include the recording and reporting of test results in the evaluation of personnel competency). Refer to D6049 (Failure to include unacceptable quality control and temperature records in the evaluation of personnel competency). Refer to D6050 (Failure to include direct observation of instrument maintenance and function checks in the evaluation of personnel competency). Refer to D6051 (Failure to include assessment of test performance through testing previously analyzed specimens or proficiency testing samples in the evaluation of personnel competency). Refer to D6052 (Failure to include assessment of problem solving skills in the evaluation of personnel competency).
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of weekly System Check Reports from 10-25-17 through 3-7-18 for the Beckman Coulter Access 2 Immunoassay System, used for patient prostate specific antigen (PSA) testing, Access 2 Immunoassay System Instructions for Use, patient test results, and lack of documentation of corrective action for failed System Checks, the technical consultant failed to ensure that patient test results were not reported until all corrective actions had been taken and the test system was functioning properly for six weeks during this time frame when a total of 380 patient PSA test results were reported. Refer to D5431 (Failure to ensure weekly System Checks were within the manufacturer's established limits before patient testing was performed).
D6048	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based on review of the CMS 209 personnel form and personnel records for testing personnel since the last survey on 4-27-16, the technical consultant failed to include, in the evaluation of the competency of the testing personnel, the recording and reporting of test results. Findings include: Review of personnel records for Testing

	Personnel #1, #2, #3, and #4 since 4-27-16 revealed the technical consultant annually evaluated the competency of testing personnel on performance of patient prostate specific antigen (PSA) testing only. The annual competency evaluations of Testing Personnel #1, #2, #3, and #4 since 4-27-16 state, "I have viewed the nurses performance of PSA's, and certify that they are proficient in performing these tests." The technical consultant failed to include, in the evaluation of the competency of the testing personnel since 4-27-16, the recording and reporting of test results.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on documentation of monthly review by the technical consultant of quality control, temperature, daily maintenance, and calibration records since the last survey on 4-27-16, freezer temperature logs since the BioRad Liquichek Immunoassay Plus Controls were put in use for PSA testing on 4-11-17, quality control (QC) records for the Beckman Coulter Access 2 Immunoassay System from 11-1-17 through 1-31-18, and personnel records, the technical consultant failed to include, in the evaluation of the competency of the testing personnel, the review of laboratory temperature records and QC records for the Access 2 Immunoassay System. Findings include: Review of documentation of monthly review by the technical consultant of quality control, temperature, daily maintenance, and calibration records since the last survey on 4-27-16 revealed the technical consultant documented monthly review of temperature records and QC records since 4-27-16. However, review of temperature logs for the freezer compartment of the laboratory refrigerator since the BioRad Liquichek Immunoassay Plus Controls were put in use for PSA testing on 4-11-17 revealed the freezer compartment daily temperatures fell outside the manufacturer's acceptable range for frozen storage of BioRad Liquichek Immunoassay Plus Controls every day the temperature was recorded from 4-11-17 through 3-7-18. Review of QC records for the Beckman Coulter Access 2 Immunoassay System from 11-1-17 through 1-31-18 revealed the Level 1 control, of two levels of control, failed to meet the manufacturer's criteria for acceptability on 12-5-17, when a total of seven patient test results were reported. Review of personnel records since 4-27-16 revealed no documentation that the technical consultant detected the unacceptable freezer storage temperature of BioRad Liquichek Immunoassay Plus Controls since 4-11-17 or unacceptable PSA control results on 12-5-17, in the evaluation of the competency of the testing personnel. Refer to D5411 (Failure to follow manufacturer's instructions for frozen storage of controls). Refer to D5481 (Failure to ensure controls were acceptable before reporting patient test results).
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

	This STANDARD is not met as evidenced by: Based on review of the CMS 209 personnel form and personnel records for testing personnel since the last survey on 4-27-16, the technical consultant failed to include, in the evaluation of the competency of the testing personnel, direct observation of performance of instrument maintenance and function checks. Refer to D5431 (Failure to ensure weekly System Checks were within the manufacturer's established limits before patient testing was performed).
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of the CMS 209 personnel form, personnel records, and proficiency testing (PT) records since the last survey on 4-27-16, the technical consultant failed to include, in the evaluation of the competency of Testing Personnel #3 and #4, assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. Refer to D2007 (Failure to rotate PT testing among testing personnel).
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of the CMS 209 personnel form and personnel records for testing personnel since the last survey on 4-27-16, the technical consultant failed to include, in the evaluation of the competency of the testing personnel, assessment of problem solving skills. Findings include: Review of personnel records for Testing Personnel #1, #2, #3, and #4 since 4-27-16 revealed the technical consultant annually evaluated the competency of testing personnel on performance of patient prostate specific antigen (PSA) testing only. The technical consultant failed to include, in the evaluation of the competency of the testing personnel since 4-27-16, assessment of problem solving skills.