

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0319979	(X3) Date Survey Completed 03/03/2020
Name of Provider or Supplier Brookhaven Urology	Street Address, City, State 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
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of daily quality control (QC) records and patient test results from the Beckman Coulter Access 2 immunoassay system from 10-1-19 through 2-27-20 and confirmation by Testing Personnel #2, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, on 3-3-20 at 1:30 p.m., the laboratory failed to include at least two levels of control on 2-14-20 when a total of seven patient prostate specific antigen (PSA) tests were performed and reported. Findings include: Review of daily QC records and patient test results from the Beckman Coulter Access 2 immunoassay system from 10-1-19 through 2-27-20 revealed the laboratory failed to include at least two levels of control on 2-14-20, when the following patient PSA tests were performed and reported: Patients #27460, #5711, #49418, #26194, #42044, #21594, #27004. Testing Personnel #2 confirmed on 3-3-20 at 1:30 p.m. that no quality control testing was performed on 2-14-20.</p>
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(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.</p>

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.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:
 Based on review of manufacturer's acceptable ranges for BioRad Liquichek Immunoassay Plus controls, daily QC records for the Beckman Coulter Access 2 immunoassay system from 10-1-19 through 2-27-20, and patient test results, the technical consultant failed to ensure the quality control program was maintained throughout the entire testing process on 2-14-20, when two levels of control were not performed, and for five days during this time frame, when at least one of two control results failed to meet the manufacturer's criteria for acceptability before reporting patient test results. Refer to D5447 (Failure to ensure two levels of control were performed each day of patient testing). Refer to D5481 (Failure to ensure two levels of control met criteria for acceptability each day of patient testing).