

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1069363	(X3) Date Survey Completed 03/19/2018
Name of Provider or Supplier Middle Tennessee Urology Specialists	Street Address, City, State 1747 Medical Center Parkway Suite #210, Murfreesboro, TN	
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
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the 2016-17 chemistry quality control (QC) records, manufacture's QC instructions, patient reports, and an interview with the lead lab nurse person, determined that the laboratory failed to perform and document at least two levels of QC materials daily with patient testing for the prostate specific antigen (PSA) in February, 2017. The findings include: 1. A lack of QC records for the PSA performed on February 10, 2017, revealed the laboratory failed to perform two levels of QC prior to testing and reporting patient results (Patient X4 of the chart audit). 2. A review of the manufactures' instructions revealed two levels of controls (MAS1-1 & MAS-3 to validate the accuracy of PSA. 3. Patient reports revealed 10 PSA patients reported without chemistry controls performed prior to testing.. 4. Interview on March 19, 2018, at approximate 11:45 AM, with the lead lab nurse person confirmed that on February 10, 2017 the two levels of chemistry PSA QC were not performed with the ten patients tested and reported.</p>