

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2285495	(X3) Date Survey Completed 12/28/2023
Name of Provider or Supplier Mississippi Urology Clinic	Street Address, City, State 1040 River Oaks Dr Ste 202, Flowood, 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 the Qualigen Fast Pack System records from installation, on 9/15 /2023 through 12/28/2023, patient testing log, lack of documentation of an Individualized Quality Control Plan (IQCP), and interview with the technical consultant (TC) at 12:00 p.m. on 12/28/2023, testing personnel failed to include at least two levels of control material each day of patient testing from 9/15/2023 through 12/28/2023. Approximately 660 prostate specific antigen (PSA) results were reported on 56 of 70 days when no QC was performed. Findings include: 1. Review of PSA quality control (QC) records from installation on 9/15/2023 through 12/28/2023 revealed QC was not performed each day when patients for PSA were tested and reported. PSA QC was performed once per week after performance verification studies were completed. 2. Review of PSA patient test records from 9/15/2023 through 12/28/2023 revealed 660 patient PSA results were reported on 56 of 70 days when no QC was performed. 3. There was no documentation of an IQCP for the Qualigen Fast Pack system, required after 1/1/16 if two levels of control are not included each day of patient testing. 4. In an interview, the laboratory TC confirmed no IQCP was written for PSA on the Qualigen Fast Pack system and QC was not performed on 56 of 70 days when patient PSA testing was performed.</p>