Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2285495	(X3) Date Survey Completed 07/22/2025
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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation of the Qualigen FastPack IP Systems in use in the laboratory on 7/22/2025 at 10:00 a.m., review of calibration and quality control records for prostate specific antigen (PSA) testing for one of three Qualigen FastPack IP Systems, Serial #0361, from 1/14/2025 through 7/11/2025, lack of documentation of verification of performance specifications, and interview with the technical consultant on 7/22/2025 at 12:20 p.m., the laboratory failed to verify performance specifications for PSA testing on the Qualigen FastPack IP System Serial #0361, before it was put in use for patient testing on 1/14/2025. Findings include: 1. Observation of the Qualigen FastPack IP Systems in use in the laboratory on 7/22/2025 at 10:00 a.m. revealed the three systems in use for PSA testing were Serial #0361, Serial #0718, and Serial #1187. 2. Review of calibration and quality control records for the Qualigen FastPack IP System Serial #0361 revealed it was put in use for PSA testing on 1/14/2025. 3. On the day of the survey, 7/22/2025, there was no documentation available for review of verification of performance specifications, to include accuracy, precision, and reportable range, for Qualigen FastPack IP System Serial #0361. 4. In an interview on 7/22/2025 at 12:20 p.m., the technical consultant confirmed that all three analyzers were used for patient testing, and performance specifications were not verified for Serial #0361 for PSA testing, before it was put in use for patient testing on 1/14/2025.

D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration and calibration verification records for the three Qualigen FastPack IP Systems in use for prostate specific antigen (PSA) testing and interview with the technical consultant on 7/22/2025 at 2:00 p.m., the laboratory failed to document, as performed, calibration verification for PSA testing at least once every six months for Serial #0718 and Serial #1187. Findings include: 1. Review of calibration records for the three Qualigen FastPack IP Systems revealed the PSA test uses only two calibrators. 2. Review of calibration verification records for Qualigen FastPack IP System Serial #0718, in use since the last survey on 12/28/2023, revealed calibration verification was not performed since 3/4/2024. Two of three calibration verifications required since 12/28/2023 were not performed. 3. Review of calibration verification records for Qualigen FastPack IP System Serial #1187, in use since 6/16 /2024, revealed calibration verification was not performed since the initial verification performed on 6/16/2024. Two of two calibration verifications required since 6/16 /2024 were not performed. 4. In an interview on 7/22/2025 at 2:00 p.m., the technical consultant confirmed that calibration verification had not been performed for Serial #0718 since 3/4/2024, and calibration verification had not been performed for Serial #1187 since 6/16/2024.