Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1049270	(X3) Date Survey Completed 06/03/2024
Name of Provider or Supplier Mcgrael Urology Associates	**Street Address, City, State** 5012 S Hwy 75 Ste 215, Denison, TX	

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
D0000	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
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 laboratory policy, American Proficiency Institute (API) proficiency testing records, laboratory's CMS 209 form, personnel records, and staff interview, the laboratory failed to ensure that patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing in the laboratory for three of three events in 2023 (Event 1, Event 2, Event 3) and one of one event in 2024 (Event 1). Findings included: 1. Review of laboratory policies revealed the laboratory did NOT have any policies for performing proficiency testing. 2. Review of the American Proficiency Institute (API) proficiency testing records revealed Testing Person-2 (TP-2) tested the following events: Chemistry Core (subspecialty endocrinology): 2023: Events 1, 2 and 3 2024 Event 1 3. Review of the laboratory's CMS 209 form revealed three Testing Persons (TP-2, TP-3, TP-4) were listed as performing moderate complexity testing (endocrinology). According to personnel records: TP-2: hire date of 11/2020 TP-3: hire date 02/07/2023 TP-4 hire date 07/25/2023 Based on these hire dates, the laboratory failed to ensure TP-3 and TP-4 participated in testing for the 2023 and 2024 events. 3. During an interview on 06/03/2024 at 10:40 am, TP-2 confirmed the laboratory failed to ensure that patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing in the laboratory.

D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Proficiency Institute (API) instructions, proficiency testing (PT) records, and confirmed in interview, the laboratory director and testing persons failed to attest to the routine integration of proficiency samples into the patient workload for two of three hematology events in 2022 (Event 2, Event 3) and three of three hematology events in 2023 (Event 1, Event 2, Event 3) and one of one hematology event in 2024 (Event 1). Findings included: 1. Review of laboratory policies revealed the laboratory did NOT have any policies for performing proficiency testing. 2. Review of API instructions revealed: "ATTESTATION STATEMENT SIGNATURES REQUIRED- For all PT results, an attestation statement must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years. Either the attestation worksheet below or this online attestation statement may be used. Electronic signatures must have evidence that only the authorized person can utilize the signature." 3. Review of hematology PT records in 2022, 2023 and 2024 revealed the testing person-1 (who was also the laboratory director) failed to sign the attestation statement for the following events: 2022: Events 2 and 3 2023: Events 1, 2 and 3 2024: Event 1 4. During an interview on 06/03/2024 at 10:40 am, TP-2 confirmed the laboratory failed to attest to the routine integration of proficiency samples into the patient workload.
D2011	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program. This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Proficiency Institute (API) proficiency testing (PT) records and confirmed in interview, the laboratory director failed to review and evaluate the results obtained in proficiency testing for two of three hematology events in 2022 (Event 2, Event 3) and three of three hematology events in 2023 (Event 1, Event 2, Event 3), one of one hematology event in 2024 (Event 1), two of three chemistry events in 2022 (Event 2, Event 3) and three of three chemistry events in 2023 (Event 1, Event 2, Event 3), and one of one chemistry event in 2024 (Event 1). Findings included: 1. Review of laboratory policies revealed the laboratory did NOT have any policies for performing proficiency testing. 2. Review of API PT records for 2022 revealed the laboratory did not ensure the laboratory director documented their review/evaluation of hematology and chemistry (subspecialty

	endocrinology) PT results, as follows: Hematology: 2022: Events 2 and 3 - PT final reports were not signed 2023: Events 1, 2 and 3 - PT final reports were not signed 2024 Event 1 - PT final report was not signed Chemistry Core (subspecialty endocrinology): 2022: Events 2 and 3 - PT final reports were not signed 2023: Events 1, 2 and 3 - PT final reports were not signed 2024 Event 1 - PT final report was not signed 3. The laboratory was asked to provide documentation of the review of the results. No documentation was provided. 4. During an interview on 06/03/2024 at 10: 40 am, TP-2 confirmed the laboratory director failed to review and evaluate the results obtained in proficiency testing.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Proficiency Institute (API) proficiency testing (PT) records, and confirmed in interview, the laboratory failed to verify the accuracy of urine sediment for two of three testing events in 2022 (Event 1, Event 3). Findings included: 1. Review of laboratory policies revealed the laboratory did NOT have any policies for performing proficiency testing. 2. Review of 2022 API PT records revealed: Event 1 a) Microscopy: Urine Sediment Score: 50 Event 3 a) Microscopy: Urine Sediment Score: 50 3. The laboratory was asked to provide documentation of performing twice annual accuracy for non-regulated analytes (urine sediment) that did not meet acceptable proficiency testing scores. No documentation was provided. 4. During an interview on 06/03/2024 at 10:40 am, TP-2 confirmed the laboratory failed to verify the accuracy of urine sediment for two of three testing events in 2022.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policies and confirmed in staff interview, it was revealed that one of one laboratory policy was not approved, signed, or dated by the laboratory director before use in May 2022. Findings included: 1. Review of the laboratory's policy manual revealed the following: An electronic mail record that stated: "The IQCP Risk Assessment and Quality Control Plan for the FastPack System at [XX] has been completed. This must be printed and approved by the Lab Director's signature." The IQCP was included in the printout. The laboratory's IQCP was not approved, signed, or dated by the laboratory director before it was placed into use in May 2022. 2. During an interview on 06/03/2024 at 11:20 am, TP-2 confirmed the above findings. Word Key: IQCP- Individualized Quality Control Plan
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)

	(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. This STANDARD is not met as evidenced by: Based on review of laboratory policies, quality control (QC) records, laboratory records, and confirmed in staff interview, the laboratory failed to monitor the accuracy and precision of FastPacK QC material over time for the PSA (prostate-stimulating antigen) analyte tested on the Qualigen FastPack analyzer four of four QC lots reviewed (random review May 2022, August 2022, October 2023, and April 2024) to ensure accurate and reliable test results. Findings included: 1. Review of laboratory policies revealed the laboratory did NOT have a procedure for monitoring the accuracy and precision of test performance over time. 2. A random review of the following lots of QC tested in May 2022, August 2022, October 2023, and April 2024 revealed no documentation of monitoring QC over time: Control Kit (level 1 and 2): Lot#2102005-1; date in use: 05/02/2022 Control Kit (level 1 and 2): Lot#2202048-1; date in use: 08/29/2023 Control Kit (level 1 and 2): Lot#2210005-1; date in use: 10/02 /2023 Control Kit (level 1 and 2): Lot#2305031-1; date in use: 04/01/2024 The laboratory was asked to provide documentation of monitoring QC over time for the PSA analyte tested on the Qualigen FastPack analyzer. None was provided. 3. Review of laboratory records revealed the laboratory had an annual volume of 600 tests performed. 4 During an interview on 06/03/2024 at 12:21 pm, Testing Person-2, confirmed the laboratory failed to monitor the accuracy and precision of FastPack QC material over time to ensure accurate and reliable test results.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid (CMS-209) form, personnel files and confirmed in interview the technical consultant (TC) failed to evaluate and document the performance two of four Testing Persons (TP-3, TP-4) responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Findings included: 1. Review of the CMS 209 form revealed three testing persons (TP #2 - TP#4) performing moderate complexity testing for PSA (prostate-specific antigen) tested on the Qualigen FastPack analyzer. 2. Review of TP-3's personnel records revealed the following: Hire date 02/27/2023 "6 Month Evaluation" performed on 8/10/23 and an "Annual Evaluation" performed on 02/08 /2024. The competency assessments were completed by TP-2 who was NOT qualified as the Technical Consultant. Review of TP-4's personnel records revealed the

	following: Hire date 07/25/2023 "6 Month Evaluation" performed on 10/25/23 and an "Annual Evaluation" performed on 04/23/2024. The competency assessments were completed by TP-2 who was NOT qualified as the Technical Consultant. The TC failed to evaluate and document the semiannual performance of TP-3 and TP-4. 3. During an interview on 06/03/2024 at 11:20 am, TP-2 confirmed she performed the semiannual competency assessments and NOT the Technical Consultant.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid (CMS-209) form, personnel records, and confirmed in interview, the Technical Consultant failed to perform annual personnel competency assessment for one of four testing persons (TP-)2 who perform moderate complexity testing in 2023. Findings: 1. Review of the CMS 209 form revealed three testing persons (TP #2 - TP#4) performing moderate complexity testing for PSA (prostate-specific antigen) tested on the Qualigen FastPack analyzer. 2. Review of personnel records revealed an annual competency assessment was NOT performed for TP-2 in 2023. 3. The laboratory was asked to provide documentation of competency assessments for 2023 and none was provided. 4. During an interview on 06/03/2024 at 11:20 am, TP-2 confirmed the above findings.