Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1049270	04/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mcgrael Urology Associates	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	An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, laboratory's Individualized Quality Control Plan (IQCP), patient records, and confirmed in

	interview, the laboratory failed to provide data in the risk assessment to support its reduction in QC frequency to every 7 days for the PSA test on the FastPack ip analyzer. Findings Included: 1. During a tour of the laboratory, the inspector observed 1 FastPack ip analyzer currently in use. 2. Review of manufacturer's instructions for the FastPack ip PSA test revealed the following: "When control testing is performed, two control levels must be used. Qualigen recommends that users run controls whenever: ..Users should follow proper state and federal quality control guidelines. See CLIA instructions. Control testing can be done once every calendar week if controls have previously passed for 30 consecutive nosiness days." 3. Review of laboratory's IQCP revealed 30 consecutive days external QC was performed in 2013. Further review revealed the laboratory failed to provide a risk assessment for the IQCP. 4. Review of laboratory QC records in March 2022 revealed the following days external QC was performed: a. 03/07/2022 b. 03/14/2022 c. 03/21/2022 d. 03/28/2022 5. Random review of patient records revealed 22 patients performed in March 2022 in which the laboratory failed to perform two levels of external quality control material at any time during the day of patient testing: a. 03/02/2022 MRN: 15324; 9513 b. 03 /03/2022 MRN: 5620; 15347 c. 03/08/2022 MRN: 17242 d. 03/09/2022 MRN: 13292 e. 03/15/2022 MRN: 17274; 16407 f. 03/16/2022 MRN: 16222 g. 03/17/2022 MRN: 3527 h. 03/18/2022 MRN: 16117; 17237 i. 03/22/2022 MRN: 17344; 11964 j. 03/23 /2022 MRN: 10479 k. 03/24/2022 MRN: 6440 l. 03/29/2022 MRN: 16620; 17122; 14788 m. 03/30/2022 MRN: 12700 n. 03/31/2022 MRN: 14606; 17372 6. In an interview with TP-1 on 04/22/2022 at 1:05 p.m., TP-1 stated they had not performed a risk assessment for the FastPack ip PSA test system prior to performing patient testing. This confirmed the above findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) -209 form, personnel records, and staff interview, the technical consultant failed to evaluate and document competency in 2021 for 1 of 1 Testing Persons (TP-1) who perform moderate complexity testing. Findings Included: 1. Review of Centers for Medicare and Medicaid (CMS -209) form submitted at time of survey (4/22/2022) revealed 1 testing person (TP-1) performing moderate complexity testing. 2. Review of laboratory personnel records revealed TP-1 had no competency documented by the technical consultant prior to performing moderate complexity testing. 3. In an interview with TP-1 on 04/22/2022 at 12:35 p.m., TP-1 stated they had no competency performed prior to performing patient testing. This confirmed the above findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Centers for Medicare and Medicaid (CMS -209) form, personnel records, and in interview with staff, it was revealed the laboratory failed to have documentation of training for the following 1 of 1 testing persons to qualify them to perform moderate complexity testing. Findings Included: 1. Review of Centers for Medicare and Medicaid (CMS -209) form submitted at time of survey (4/22/2022) revealed 1 testing person (TP-1) performing moderate complexity testing. 2. Review of laboratory personnel records revealed TP-1 had no training prior to performing moderate complexity testing. 3. In an interview with TP-1 on 04/22 /2022 at 12:35 p.m., TP-1 stated they had no training prior to performing patient testing. This confirmed the above findings.