

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1049270	(X3) Date Survey Completed 05/11/2026
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	An announced routine recertification survey of the laboratory was completed on 05/11/2026. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. Standard level deficiencies were cited.
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute proficiency testing records, and confirmed in staff interview, the laboratory failed to have documentation of evaluating proficiency testing results returned as "not graded" by the proficiency testing agency for one of six Chemistry proficiency testing events from 2024 to 2026. Findings include: 1. Review of the laboratory's American Proficiency Institute Chemistry Core proficiency testing records from 2024 (events 1, 2, and 3), 2025 (events 1, 2, and 3), and 2026 (event 1) determined the following proficiency testing results returned as "not graded" by the proficiency testing agency: a. 2025 Event 2 Prostate Specific Antigen (PSA) Sample: IA-09 2. Further review of the laboratory's proficiency testing records determined the laboratory failed to have documentation of evaluating "not graded" results returned by the proficiency testing agency. 3. Testing person-1 (as listed on the CMS-209 form) confirmed the findings in an interview on 05/11/2026 at 1105 hours in the office. Key:CMS - Centers for Medicare and Medicaid Services</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p>

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's environmental logs, review of patient test results, and confirmed in interview, the laboratory failed to have documentation for environmental conditions for 3 of 18 days in March 2025. Findings include: 1. Review of the laboratory's environmental logs determined the laboratory established the following ranges for the laboratory's environmental conditions: Refrigerator: 2-8 degrees Celsius Room Temperature: 15-32 degrees Celsius Relative Humidity: 10-80 % 2. Further review of the laboratory's environmental logs determined the laboratory failed to have documentation for the laboratory's environmental conditions for 3 of 18 days in March 2025: Day 26 Day 27 Day 28 3. Review of patient test records determined 15 patient tests were performed on days in which environmental conditions were not documented: a. Day 26: Patient ID: 14090 Patient ID: 15533 Patient ID: 12245 Patient ID: 21157 Patient ID: 13585 Patient ID: 19028 Patient ID: 8556 Patient ID: 20217 Patient ID: 8436 b. Day 27: Patient ID: 20999 Patient ID: 9513 Patient ID: 15537 Patient ID: 13558 Patient ID: 20392 Patient ID: 18198 4. Testing person-1 (as listed on the CMS-209 form) confirmed the findings in an interview on 05/11/2026 at 1242 hours in the office. Key: CMS - Centers for Medicare and Medicaid Services

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on surveyor direct observation of reagents in use by the laboratory, and confirmed in interview, the laboratory failed to ensure expired materials were not used for testing. Findings include: 1. Direct surveyor observation on 05/11/2026 at 1355 hours identified four expired bottles of urinalysis test strips: Siemens Multistix 10SG Lot: 409055 Expiration date: 03/31/2026 2. Further observation identified one expired test kit: Qualigen FastPack TPSA Method Verification Kit Lot: 2502033-1 Expiration date: 02/27/2026 3. Testing person-1 (as listed on the CMS-209 form) confirmed the findings in an interview on 05/11/2026 at 1400 hours in the office. Key: CMS - Centers for Medicare and Medicaid Services

D5463

CONTROL PROCEDURES
CFR(s): 493.1256(d)(7)(g)

(d)(7) Over time, rotate control material testing among all operators who perform the

test.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's Centers for Medicare and Medicaid Services (CMS) form 209, review of the laboratory's quality control records, and confirmed in interview, the laboratory failed to ensure quality control testing was rotated among all personnel performing non-waived chemistry testing for 99 of 102 events from June 2024 to April 2026. Findings include: 1. Review of the laboratory's submitted form CMS-209 determined the laboratory had two testing persons performing non-waived chemistry testing: testing person-1 (TP-1), and testing person-2 (TP-2). 2. Review of the laboratory's quality control logs from June 2024 to April 2026 determined the quality control logs were documented by one of two testing persons for 99 of 102 events: a. June 2024 06/03/2024: TP-2 (Alias "KT") 06/10/2024: TP-2 06/17/2024: TP-2 06/24/2024: TP-2 b. July 2024: 07/01/2024: TP-2 07/09/2024: TP-2 07/15/2024: TP-2 07/22/2024: TP-2 07/29/2024: TP-2 c. August 2024: 08/05/2024: TP-2 08/12/2024: TP-2 08/19/2024: TP-2 08/26/2024: TP-2 d. September 2024: 09/02/2024: TP-2 09/09/2024: TP-2 09/16/2024: TP-2 09/23/2024: TP-2 09/30/2024: TP-2 e. October 2024: 10/01/2024: TP-2 10/07/2024: TP-2 10/14/2024: TP-2 10/21/2024: TP-2 10/28/2024: TP-2 f. November 2024: 11/01/2024: TP-2 11/04/2024: TP-2 11/11/2024: TP-2 11/18/2024: TP-2 11/25/2024: TP-2 g. December 2024: 12/02/2024: TP-2 12/09/2024: TP-2 12/16/2026: TP-2 12/23/2024: TP-2 12/30/2024: TP-2 h. January 2025: 01/06/2025: TP-2 01/13/2025: TP-2 01/20/2025: TP-2 01/27/2025: TP-2 i. February 2025: 02/03/2025: TP-2 02/10/2025: TP-2 02/17/2025: TP-2 02/24/2025: TP-2 j. March 2025: 03/03/2025: TP-2 03/10/2025: TP-2 03/17/2025: TP-2 03/24/2025: TP-2 k. April 2025: 04/07/2025: TP-2 04/14/2025: TP-2 04/21/2025: TP-2 l. May 2025: 05/05/2025: TP-2 05/12/2025: TP-2 05/19/2025: TP-2 05/26/2025: TP-2 m. June 2025: 06/02/2025: TP-2 06/09/2025: TP-2 06/16/2025: TP-2 06/23/2025: TP-2 06/30/2025: TP-2 n. July 2025 07/07/2025: TP-2 07/14/2025: TP-2 07/21/2025: TP-2 07/28/2025: TP-2 o. August 2025: 08/04/2025: TP-2 08/11/2025: TP-2 08/18/2025: TP-2 08/25/2025: TP-2 p. September 2025: 09/02/2025: TP-2 09/08/2025: TP-2 09/15/2025: TP-2 09/22/2025: TP-2 09/29/2025: TP-2 q. October 2025: 10/06/2025: TP-2 10/13/2025: TP-2 10/20/2025: TP-2 10/27/2025: TP-2 r. November 2025: 11/03/2025: TP-2 11/10/2025: TP-2 11/17/2025: TP-2 11/24/2025: TP-2 s. December 2025 12/08/2025: TP-2 12/15/2025: TP-2 12/22/2025: TP-2 12/29/2025: TP-2 t. January 2026 01/05/2026: TP-2 01/12/2026: TP-2 01/19/2026: TP-2 01/26/2026: TP-2 u. February 2026: 02/02/2026: TP-2 02/09/2026: TP-2 02/16/2026: TP-2 02/23/2026: TP-2 v. March 2026: 03/02/2026: TP-2 03/09/2026: TP-2 03/16/2026: TP-2 03/23/2026: TP-2 03/30/2026: TP-2 w. April 2026: 04/06/2026: TP-2 04/13/2026: TP-2 04/22/2026: TP-2 04/27/2026: TP-2 The surveyor asked TP-1 who the initials "KT" were, as was documented on the quality control logs. TP-1 stated the initials "KT" were TP-2 (as listed on the CMS-209 form). 3. Testing person-1 (as listed on the CMS-209 form) confirmed the findings in an interview on 05/11/2026 at 1200 hours in the office. Key: CMS - Centers for Medicare and Medicaid Services