

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0714209	(X3) Date Survey Completed 07/25/2025
Name of Provider or Supplier Central Wyoming Urological Associates, Pc	Street Address, City, State 1416 E A Street, Casper, WY	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records and staff interview, the laboratory director or the laboratory director's designee failed to attest to the routine integration of proficiency tests into the patient workload for 5 out of 17 API (American Proficiency Institute) proficiency testing events reviewed from July 2023 through July 2025. The findings were: 1. Review of the laboratory's proficiency testing records showed API testing events 2023 Microbiology event #2, 2023 Microbiology event #3, 2023 Chemistry Core event #3, 2025 Microbiology event #1, and 2025 Hematology event #1 failed to include an attestation statement signed by the laboratory director or the laboratory director's designee. 2. Interview with the technical supervisor and the general supervisor on 7/25/25 at 10:37 AM confirmed the attestation statements were incomplete.</p>
D2014	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.</p>

This STANDARD is not met as evidenced by:
Based on review of proficiency testing records and staff interview, the laboratory failed to maintain a copy of each step in the testing and reporting process for 2 of 17 (2023 Microbiology event #3, 2024 Hematology event #3) American Proficiency Institute (API) proficiency testing events reviewed from July 2023 through July 2025. The findings were: 1. Review of the proficiency testing records showed no evidence of the following documentation: a. The 2023 API Microbiology event #3 documentation failed to include the attestation statement and the testing worksheets. b. The 2024 API Hematology event #3 documentation failed to include the attestation statement, the submission forms, and the testing worksheets. 2. Interview with the technical supervisor and general supervisor on 7/25/25 at 11:13 AM confirmed no further documentation was available.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on review of the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, review of personnel records, lack of documentation, review of policy and procedure, and staff interview, the laboratory failed to implement their competency assessment policy to ensure the competency of the staff members holding the positions of technical supervisor and general supervisor for 2 of 2 years reviewed (2023, 2024). The findings were: 1. Review of the CMS 206 Laboratory Personnel Report showed the laboratory listed one staff member as the general supervisor and one staff member as the technical supervisor. 2. Review of the personnel records for the general supervisor and the technical supervisor showed no evidence a competency assessment had been completed in 2023 or 2024. 3. Interview with the technical supervisor and general supervisor on 7/25/25 at 11:32 AM confirmed the competency assessments had not been completed. 4. Review of the Competency Assessment Policy, dated 5/15/23, showed "...The laboratory director must perform initial, 6-month, and annual competency assessment (sic) of the technical supervisor/general supervisor..."

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:
Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory failed to have a system in place for reviewing proficiency

test results that received an artificial score of 100% for 7 out of 17 API (American Proficiency Institute) proficiency testing events reviewed from July 2023 through July 2025. The findings were: 1. Review of the 2023 Microbiology event #2 comparative evaluation report showed the laboratory received an artificial score of 100% on sample UTI-08 for the detection of Citrobacter species and on sample UTI-09 for the detection of Candida species. In addition, the laboratory received an artificial score of 100% on the detection of molecular resistant genes for 35 of 35 sample sets reported. There was no documentation the results of the proficiency testing event had been evaluated for accuracy. 2. Review of the 2023 Microbiology event #3 comparative evaluation report showed the laboratory received an artificial score of 100% on sample UTI-14 for the detection of Ureaplasma urealyticum. In addition, the laboratory received an artificial score of 100% on the detection of molecular resistant genes for 7 out of 7 sample sets reported. There was no documentation the results of the proficiency testing event had been evaluated for accuracy. 3. Review of the 2024 Microbiology event #1 comparative evaluation report showed the laboratory received an artificial score of 100% on the detection of molecular resistant genes for 18 out of 18 sample sets reported. There was no documentation the results of the proficiency testing event had been evaluated for accuracy. 4. Review of the 2024 Microbiology event #2 comparative evaluation report showed the laboratory received an artificial score of 100% on the detection of molecular resistant genes for 19 out of 19 sample sets reported. There was no documentation the results of the proficiency testing event had been evaluated for accuracy. 5. Review of the 2024 Microbiology event #3 comparative evaluation report showed the laboratory received an artificial score of 100% on the detection of molecular resistant genes for 19 out of 19 sample sets reported. There was no documentation the results of the proficiency testing event had been evaluated for accuracy. 6. Review of the 2025 Microbiology event #1 comparative evaluation report showed the laboratory received an artificial score of 100% on the detection of molecular resistant genes for 4 of 19 sample sets reported. There was no documentation the results of the proficiency testing event had been evaluated for accuracy. 7. Review of the 2025 Microbiology event #2 comparative evaluation report showed the laboratory received an artificial score of 100% on the detection of molecular resistant genes for 1 out of 12 sample sets reported. There was no documentation the results of the proficiency testing event had been evaluated for accuracy. 8. Interview with the technical supervisor and general supervisor on 7/25/25 at 10:37 AM confirmed no further documentation was available.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:
Based on review of API (American Proficiency Institute) proficiency testing records, lack of documentation, and staff interview, the laboratory failed to review and evaluate proficiency testing results for 4 out of 17 proficiency testing events reviewed from July 2023 through July 2025. The findings were: 1. Review of the API proficiency testing reports failed to include documentation the laboratory had evaluated test scores of less than 100%. The following concerns were identified: a. Review of the 2023 Microbiology event #2 comparative evaluation showed the laboratory had a total score of 98% on the molecular bacteriology urine sample set and a total score of 99% on the molecular resistant gene sample set. There was no documentation the laboratory had evaluated the results to determine the cause of the

failure. b. Review of the 2023 Microbiology event #3 comparative evaluation showed the laboratory had a total score of 99% on the molecular bacteriology urine sample set. There was no documentation the laboratory had evaluated the results to determine the cause of the failure. c. Review of the 2024 Microbiology event #2 comparative evaluation showed the laboratory had a total score of 99% on the molecular bacteriology urine sample set. There was no documentation the laboratory had evaluated the results to determine the cause of the failure. d. Review of the 2025 Microbiology event #1 comparative evaluation showed the laboratory had a total score of 97% on the molecular bacteriology urine sample set and a total score of 97% on the molecular resistant gene sample set. There was no documentation the laboratory had evaluated the results to determine the cause of the failure. 2. Interview with the technical supervisor and general supervisor on 7/25/25 at 9:32 AM confirmed the unsatisfactory proficiency testing scores had not been thoroughly investigated and documented.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

(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 the CMS-116 form, procedure manual review, and staff interview, the current laboratory director failed to sign and date as approved 1 of 1 policy and procedure related to competency assessments. The findings were: 1. Review of the Competency Assessment Policy, dated 5/15/23, failed to include the current laboratory director's signature and date of approval. Review of the laboratory's procedure manuals showed the current laboratory director had signed and approved the procedure using a coversheet; however, the competency assessment procedure was not included on the list. 2. Review of the CMS-116 form, received on 6/11/24, showed a change of the laboratory director, effective 5/1/24, was approved on 6/26/24. 3. Interview with the technical supervisor and general supervisor on 7/25/25 at 11:35 AM revealed the competency assessment procedure was located in a separate binder and confirmed it had not been reviewed and approved by the current laboratory director.