

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0714209	(X3) Date Survey Completed 03/22/2023
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>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, and staff interview, the laboratory failed to establish policies and procedures to assess the competency of the positions of technical supervisor, general supervisor, and the testing personnel for 1 of 1 year reviewed (2022). The findings were: 1. Review of the CMS 209 Laboratory Personnel Report showed employee #1 held the position of technical supervisor (TS), general supervisor and testing personnel (TP). Review of employee #1's personnel record showed no evidence competency assessments had been completed in 2022 for any of the responsibilities held by employee #1. 2. Review of the personnel record for TP #2 showed an initial competency assessment had been completed on 5/26/23. There was no evidence a 6 month competency assessment had been completed. 3. Review of the laboratory's documentation showed no evidence a policy and procedure had been developed. 4. Interview with the TS on 3/22/23 at 9:51 AM confirmed a policy and procedure for competency assessments had not been developed and, in addition, confirmed the competency assessments had not been completed.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory's test menu, lack of documentation, and staff interview, the laboratory failed to at least twice annually verify the accuracy of the post-vasectomy semen analysis (PVSA) test method for 1 of 1 year reviewed (2022). The laboratory performed approximately 38 PVSA patient tests per year. The findings were: 1. Review of the laboratory's documentation showed PVSA was added to the test menu on 4/4/22. 2. Review of the laboratory's records showed no evidence PVSA patient tests had been verified for accuracy at least twice annually. 3. Interview with the technical supervisor on 3/22/23 at 10:05 AM confirmed the accuracy of the PVSA test had not been verified as required.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 lack of documentation and staff interview, the laboratory failed to verify the accuracy of the test method prior to patient testing for 1 of 1 new test verification studies reviewed (post-vasectomy semen analysis). The laboratory performed approximately 38 post-vasectomy semen analyses per year. The findings were: 1. Review of the laboratory's documentation showed no evidence the post-vasectomy semen analysis test had been verified to ensure the expected results were obtained prior to testing patient samples. 2. Interview with the technical supervisor on 3/22/23 at 10:05 AM confirmed a verification study had not been completed.