Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2254056	08/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Cheyenne Urological Lab	2003 Bluegrass Circle, Cheyenne, 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	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 proficiency testing records, lack of documentation, and staff interview, the testing personnel (TP) and the laboratory director (LD) failed to attest to the routine integration of proficiency tests into the patient workload for 3 of 3 American Proficiency Institute (API) proficiency testing events reviewed from July 2022 through July 2023. The findings were: 1. Review of the API proficiency testing records failed to include the signatures of the TP and the LD on the attestation statement for the following events: a. Microbiology 2022 event #2 b. Microbiology 2022 event #3 c. Microbiology 2023 event #1 2. Interview with the technical supervisor on 8/18/23 at 2:24 PM confirmed the attestation statements for the proficiency testing events had not been signed.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) 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. (6) PT is required for only the test

	system, assay, or examination used as the primary method for patient testing during the PT event. 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 of the API (American Proficiency Institute) proficiency testing process for 3 of 3 proficiency testing events reviewed from July 2022 through July 2023. The findings were: 1. Review of the proficiency testing records showed no evidence of the following documentation: a. The 2022 API Microbiology 2nd Event failed to include the submission form, the testing worksheet, the signed attestation statement, documentation of the investigation of the 0% score for Mycoplasma genitalium, and documentation the laboratory director had reviewed the performance evaluation. b. The 2022 API Microbiology 3rd Event failed to include the submission form, the testing worksheet, the signed attestation statement, documentation of the reason sample # MPG-05 was not graded due to a "Lab reported test problem", and documentation the laboratory director had reviewed the performance evaluation. c. The 2023 API Microbiology 1st Event failed to include the submission form, the testing worksheet, the signed attestation statement, and documentation the laboratory director had reviewed the performance evaluation. 2. Interview with the technical supervisor on 8/18/23 at 2:24 PM confirmed the proficiency testing documentation was incomplete.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing records, lack of documentation, and staff interview, the laboratory failed to review and evaluate proficiency testing results for 3 of 3 testing events reviewed from July 2022 through July 2023. The findings were: 1. Review of the API proficiency testing records failed to include documentation the laboratory had evaluated the testing results for the following events: a. 2022 Microbiology 2nd event. b. 2022 Microbiology 3rd event. c. 2023 Microbiology 1st event. 2. Interview with the technical supervisor on 8/18/23 at 2:24 PM confirmed the proficiency testing documentation was incomplete.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on observation, policy and procedure review, and staff interview, the laboratory failed to ensure 2 of 2 centrifuges in use were verified for accuracy as defined in the policy and procedure. The findings were: 1. Observation of the laboratory showed a VWR microplate microcentrifuge and a VWR 15000 RPM (revolutions per minute) microcentrifuge were in use. 2. Review of the laboratory's standard operation procedure manual, dated 6/14/22, showed "...15.3.1 The centrifuge used to extract the samples must be verified annually..." There was no documentation the laboratory had verified the accuracy of the microcentrifuges as required. 3. Interview with the technical supervisor on 8/18/23 at 3:05 PM confirmed the accuracy of the microcentrifuges had not been verified as required.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) record review, review of the patient testing log, and staff interview, the laboratory failed to perform a positive and negative control each day of patient testing from 8/1/22 through 4/17/23 for the Applied Biosystems QuantStudio 3 Real-Time PCR System which included the identification of 18 types of bacteria and 4 types of yeast. This failure affected 85 patient tests. The laboratory performed 128 patient tests during this time period. The findings were: 1. Review of the QC records and the patient testing log showed the laboratory failed to perform a positive and a negative control for the following: a. During August of 2022 QC was not performed as required on 8/4, 8/19, 8/24, and 8/26 which affected 5 patient samples. b. During September of 2022 QC was not performed as required on 9/9, 9 /21, and 9/27 which affected 5 patient samples. c. During November of 2022 QC was not performed as required on 11/17, 11/18, and 11/29 which affected 14 patient samples. d. During December of 2022 QC was not performed as required on 12/1, 12 /2, 12/8, 12/9, and 12/23 which affected 9 patient samples. e. During January of 2023 QC was not performed as required on 1/5, 1/6, 1/9, 1/10, 1/12, 1/19, 1/20, and 1/31 which affected 22 patient samples. f. During February of 2023 QC was not performed as required on 2/1, 2/2, 2/9, 2/10, and 2/17 which affected 16 patient samples. g. During March of 2023 QC was not performed as required on 3/30 and 3/31 which affected 12 patient samples. h. During April of 2023 QC was not performed as required on 4/12 and 4/17 which affected 2 patient samples. 2. There was no evidence an individualized quality control plan (IQCP) had been developed. 3. Interview with the technical supervisor on 8/18/23 at 2:43 PM revealed the laboratory performed external QC once a week and an IQCP had not been established.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.

	1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) records, lack of documentation, staff interview, and review of quality control records, the patient testing log, personnel records, quality assurance documentation and policy and procedures, the laboratory director failed to attest to the routine integration of proficiency tests into the patient workload (D6089); failed to ensure proficiency testing events were processed and returned to the proficiency testing program within the established timeframe (D6090); failed to review and evaluate PT testing results (D6091); failed to ensure a quality control program was established to ensure the quality of laboratory results (D6093); failed to ensure a quality assurance program was maintained (D6094); and failed to ensure policy and procedures were developed and followed to ensure the competency of testing personnel, the general supervisor, and the technical supervisor (D6103).
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the proficiency testing records, lack of documentation, and staff intervew, the laboratory director failed to attest to the routine integration of proficiency tests into the patient workload for 3 of 3 American Proficiency Institute (API) proficiency testing events reviewed from July 2022 through July 2023. Refer to D2009.
D6090	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(ii) The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and staff interview, the laboratory director failed to ensure 1 of 4 proficiency testing events (2023 American Proficiency Institute (API) Microbiology 2nd Event) reviewed was processed and returned to the proficiency testing program within the established timeframe. The findings were: 1. Review of the laboratory's proficiency testing records showed a packing slip for the API 2023 Microbiology 2nd event. There was no documentation the proficiency testing samples had been processed and the results returned to the proficiency testing program. Review of the proficiency testing results retrieved from the API website showed the laboratory failed to participate in the event. 2. Interview with the technical supervisor on 8/18/23 at 2:24 PM revealed he did not recall receiving the proficiency testing samples.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)

	The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute proficiency testing (PT) records, lack of documentation, and staff interview, the laboratory director failed to review and evaluate PT testing results for 3 of 3 testing events reviewed from July 2022 through July 2023. Refer to D5211.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on quality control record review, review of the patient testing log, and staff interview, the laboratory director failed to ensure a quality control program was established to ensure the quality of laboratory services provided. Refer to D5449.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation, and staff interview, the laboratory director failed to ensure the laboratory had maintained a quality assurance program for general laboratory, pre-analytic, analytic, and post-analytic systems for the specialty of Microbiology. The findings were: 1. Review of the laboratory's standard of operation manual, dated 6/14/23, showed "...14.0 Corrective Actions Corrective actions will be written for any of the following errors made in the pre-analytic, analytic, or post-analytic state of testing. Corrective actions are initiated and tracked at the laboratory site..." Review of the laboratory's documentation showed the last quality assessment was completed on 5/23/22. 2. Interview with the technical supervisor on 8/18/23 at 3:31 PM confirmed there was no additional documentation.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or

	continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of personnel records, lack of documentation, and staff interview, the laboratory director failed to ensure policies and procedures were established to assess the competency of the technical supervisor, general supervisor, and testing personnel. The laboratory employed one staff member to fulfill the duties of each position. The findings were: 1. Review of staff #1's personnel record showed his last competency assessment had been completed on 3/8/21. 2. Interview with staff #1 on 8/18/23 at 3: 31 PM revealed he was the sole employee of the laboratory, performed patient testing, was the general supervisor, and was also the technical supervisor. Staff #1 confirmed no competency assessments had been completed and was unable to locate a policy and procedure.