Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2188511	07/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Big Horn Pediatrics & Family Medicine	106 West Angus, Buffalo, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the UriCult (culture method to detect urinary pathogens) patient testing log, lack of documentation, and staff interview, the laboratory failed to enroll in an approved proficiency testing program for the regulated bacteriology test system for 10 months of patient testing (9/25/20 through 7/21/21). The laboratory performed 11 UriCult tests in 10 months of testing. The findings were: 1. Review of the UriCult patient testing log showed 11 cultures had been performed from 9/25/20 to 7/21/21. Review of the laboratory's documentation showed no evidence the laboratory was enrolled in proficiency testing. 2. Interview with the technical consultant on 7/22/21 at 2:35 PM confirmed the laboratory had not enrolled in a proficiency testing program.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During

	the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to report 89 out of 89 SARS-CoV-2 test results as required for 10 months of testing (September 2020 through July 2021). The findings were: 1. Review of the laboratory's documentation showed 25 SARS-CoV-2 tests were performed using the BD Veritor Rapid SARS-CoV-2 test system and 64 SARS-CoV-2 tests were performed using the Abbott ID Now COVID-19 test system since September 2020. There was no evidence the test results had been reported to the State Public Health Laboratory. 2. Interview with the technical supervisor on 7/22/21 at 3 PM confirmed the negative SARS-CoV-2 patient test results had not been reported as required. In addition, the technical supervisor stated positive SARS-CoV-2 patient results had been reported, however the laboratory was unable to verify the positive results had been transmitted to the State Public Health Laboratory.
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation, lack of documentation, medical record review, review of the UriCult patient testing log, review of the UriCult manufacturer's instructions for use, and staff interview, the laboratory failed to establish a policy and procedure to ensure positive identification of patient samples (D5203), failed to develop a policy and procedure for the UriCult test system (D5401), failed to follow manufacturer's instructions (D5411), failed to ensure the UriCult test system was verified for precision and accuracy prior to testing patient samples (D5421), and failed to perform quality control on the UriCult test media with each new lot number or shipment (D5445).
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on observation, lack of documentation, and staff interview, the laboratory failed to establish policies and procedures to ensure positive identification of a patient's specimen from the time of collection, through the completion of testing, and reporting

	results for 1 patient sample reviewed. The laboratory performed 11 UriCult (culture method to detect urinary pathogens) tests since 9/25/20. The findings were: 1. Observation on 7/22/21 at 2:15 PM showed an unlabeled UriCult culture tube was in the incubator. 2. Review of the laboratory's records showed no evidence a written policy and procedure had been established to ensure positive identification of a patient's specimen. 3. Interview with the technical consultant on 7/22/21 at 3 PM confirmed the UriCult culture tube was not labeled with the patient's name or other identifier. The specimen was discarded at that time.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to have written procedures for the UriCult (culture method to detect urinary pathogens) moderate complexity test and a procedure for reporting SARS-CoV-2 positive and negative test results. The laboratory performed 11 UriCult tests and 89 SARS-CoV-2 tests since 9/25/20. The findings were: 1. Review of the laboratory's procedure manuals showed no evidence the laboratory had developed a policy and procedure for the UriCult test system and for reporting SARS-CoV-2 positive and negative test results to the appropriate agencies. 2. Interview with the technical consultant on 7/22 /21 at 3 PM confirmed the laboratory did not have written procedures for the UriCult or for reporting SARS-CoV-2 test results.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on medical record review, review of the UriCult (culture method to detect urinary pathogens) patient testing log, review of the UriCult instructions for use, and staff interview, the laboratory failed to follow the manufacturer's instructions on the incubation time required before reporting patient results. The laboratory performed 11 UriCult tests from 9/25/20 to 7/21/21. The findings were: 1. Review of the medical record for patient #1 showed a UriCult test was ordered on 9/23/20. Review of the UriCult patient testing log showed positive growth was reported on 9/25/20 (approximately 48 hours). The medical record and the patient testing log failed to show a collection time and the time the result was reported. 2. Review of the UriCult instructions for use showed the UriCult should be incubated for 16 to 24 hours with negative cultures and complicated or catheter-associated urinary tract infection samples incubated for an additional 24 hours to ensure that slow-growing bacteria were detected. 3. Interview with the technical consultant on 7/22/21 at 3 PM

	confirmed the laboratory had not been following the manufacturer's instructions in regard to incubation time.
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 and precision of the UriCult (culture method to detect urinary pathogens) test system prior to patient testing. The laboratory had performed 11 UriCult tests from 9/25/20 to 7/21/21. The findings were: 1. Review of the laboratory's records showed no evidence a verification study had been completed for the UriCult test system, 2. Interview with the technical consultant on 7/22/21 at 3 PM confirmed the verification study had not been completed.
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 lack of documentation and staff interview, the laboratory failed to check each lot number or shipment of UriCult (culture method to detect urinary pathogens) prior to testing patient samples. The laboratory performed 11 UriCult tests from 9/25/20 to 7/21/21. The findings were: 1. Review of the laboratory's records showed no evidence each lot number or shipment of UriCult media was checked to ensure the media was capable of supporting growth of both gram-positive and gram-negative microorganisms prior to testing patient samples. 2. Interview with the technical consultant on 7/22/21 at 3 PM confirmed quality control checks had not been performed on the UriCult media.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance

	with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Review of the CMS-209 Laboratory Personnel Report, review of the laboratory's records, medical record review, review of the UriCult patient testing log, review of the UriCult instructions for use, lack of documentation, and staff interview, the lab director failed to ensure the UriCult test system was verified for accuracy and precision prior to patient testing (D6013); failed to ensure testing personnel followed the manufacturer's instructions (D6014); failed to ensure the laboratory enrolled in proficiency testing (D6015); failed to ensure quality control of test system media was performed (D6020); failed to ensure a quality assurance plan had been developed (D6021); and failed to ensure competency assessments were completed for the testing personnel and the technical consultant (D6030).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory director failed to ensure the UriCult (culture method to detect urinary pathogens) test system was verified for accuracy and precision prior to patient testing. The laboratory had performed 11 UriCult tests from 9/25/20 to 7/21/21. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on medical record review, review of the UriCult (culture method to detect urinary pathogens) patient testing log, review of the UriCult instructions for use, and staff interview, the laboratory director failed to ensure the testing personnel followed the manufacturer's instructions on the incubation time required before reporting patient results. The laboratory performed 11 UriCult tests from 9/25/20 to 7/21/21. Refer to D5411.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of the UriCult (culture method to detect urinary pathogens) patient testing log, lack of documentation, and staff interview the laboratory director failed to ensure the laboratory was enrolled in an approved proficiency testing program for the regulated subspecialty of bacteriology. The laboratory performed 11 UriCult tests from 9/25/20 through 7/21/21. Refer to D2000.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory director failed to ensure the quality of each lot number and shipment of the UriCult (culture method to detect urinary pathogens) test system was verified prior to patient testing. The laboratory performed 11 UriCult tests since 9/25/20. Refer to D5445.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, lack of documentation and staff interview, the laboratory director failed to ensure the laboratory had established a quality assessment plan for general laboratory, pre-analytic, analytic, and post-analytic systems for the subspecialty of bacteriology. The findings were: 1. Review of the laboratory's records showed no evidence a quality assurance plan had been developed which included the items the laboratory reviews, the frequency of review, and the method they used to document the review. 2. Interview with the technical

	consultant on 7/22/21 at 3 PM revealed the laboratory had not established a quality assessment plan.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) 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 the CMS-209 Laboratory Personnel Report, lack of documentation, and staff interview, the laboratory director failed to ensure the competency of personnel performing test procedures and the competency of the technical consultant. The laboratory employed 2 testing personnel and 1 technical consultant. The findings were: 1. Review of the CMS-209 Laboratory Personnel Report showed the laboratory employed 2 testing personnel who performed moderate complexity testing and 1 technical consultant. 2. Review of the laboratory's records showed no documentation competency assessments had been completed prior to patient testing for the testing personnel or a competency assessment completed for the technical consultant. 3. Interview with the technical consultant on 7/22/21 at 3 PM confirmed the competency assessments had not been completed.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the CMS-209 Laboratory Personnel Report, lack of documentation, and staff interview, the laboratory failed to ensure testing personnel were qualified to perform moderate complexity testing on the UriCult test system (D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a

	chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review personnel files, lack of documentation, and staff interview, the laboratory failed to ensure 1 testing personnel (TP) had the appropriate education required prior to testing patient specimens (TP #2). The findings were: 1. Review of the personnel files for TP #2 showed no evidence of the testing personnel's transcripts or diploma to show the employee met the required qualification. 2. Interview with the technical consultant on 7/22/21 at 3 PM confirmed the employee's diploma or transcripts were not available.