Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0663229	05/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Big Horn Pediatrics Pc	1308 West 4th Street, Gillette, 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 proficiency testing records, lack of documentation, review of the patient test log sheet, and staff interview the laboratory failed to ensure testing personnel who routinely perform patient testing participated in the proficiency testing events (D2007), failed to ensure testing personnel signed the attestation statement (D2009), and failed to maintain a copy of the proficiency testing results (D2015). .
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: . Based on review of the proficiency testing records, review of the patient test log sheet, and staff interview, the laboratory failed to rotate the testing personnel

	performing AAB (American Association of Bioanalysts) Bacteriology proficiency testing for 5 of 5 proficiency testing events reviewed (2019 Event #3, 2020 Event #1, 2020 Event #2, 2020 Event #3, 2021 Event #1). The findings were: 1. Review of AAB Bacteriology proficiency testing records for 2019 Event #3, 2020 Event #1, 2020 Event #2, 2020 Event #3, and 2021 Event #1 showed the attestation statement for each event was signed by MD #1 and TP (testing personnel) #6. 2. Review of the "Urine Culture Growth Record" patient test log sheet showed testing was performed by MD #2, NP (nurse practitioner) #1, NP #2, PA (physician assistant) #1, TP #2, TP #3, TP #4, and TP #5. 3. Interview with the laboratory manager on 5/9/22 at 1:50 PM revealed she was new to the position and was unaware of the regulation. The laboratory director was unavailable. .
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 individual testing the proficiency testing samples failed to attest to the routine integration of the American Association of BioAnalysts (AAB) proficiency tests into the patient workload for 1 of 6 proficiency testing events reviewed from November 2019 through November 2021. The findings were: 1. Review of the AAB Bacteriology 2021 Event #2 proficiency testing records failed to include the signature of the testing personnel performing the test. There was no documentation available to identify the testing personnel that performed the proficiency testing event. 2. Interview with the laboratory manager on 5/9/22 at 1:50 PM revealed she was new to the position and was unaware of the regulation. The laboratory director was unavailable. .
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, review of the patient test log sheet, and staff interview, the laboratory failed to maintain a copy of the testing results for the AAB (American Association of Bioanalysts) proficiency testing samples for 5 of 6 proficiency testing events reviewed (AAB 2019 Event #3, AAB 2020 Event #2, AAB

	2020 Event #3, AAB 2021 Event #1, AAB 2021 Event #2). The findings were: 1. Review of the proficiency testing records for 2019 Event #3, 2021 Event #1, and 2021 Event #2 showed the results of the tests were documented on undated and unsigned Post-it Notes. There was no documentation of the test results for 2020 Event #2 and 2020 Event #3. 2. Review of the 11/15/19 through 5/4/22 "Urine Culture Growth Record" patient testing log sheet showed no documentation of the proficiency testing samples. 3. Interview with the laboratory manager on 5/9/22 at 1:50 PM revealed she was new to the position and was unaware of the regulation. The laboratory director was unavailable. .
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 proficiency testing records, lack of documentation, and staff interview, the laboratory failed to review and evaluate proficiency testing results for 5 of 6 testing events from the 3rd event of 2019 through 2021. The findings were: 1. Review of the AAB (American Association of Bioanalysts) proficiency testing (PT) reports failed to include documentation the laboratory had evaluated test scores of less than 100% and the laboratory director had reviewed the results. The following concerns were identified: a. Review of the 2019 AAB Bacteriology Event #3 PT results showed the laboratory scored an 80%. There was no documentation the laboratory had evaluated the proficiency testing results. b. Review of the 2020 AAB Bacteriology Event #2 PT results showed the laboratory scored an 80%. There was no documentation the laboratory had evaluated the proficiency testing results. c. Review of the 2020 AAB Bacteriology Event #3 PT results showed the laboratory scored an 80%. There was no documentation the laboratory had evaluated the proficiency testing results. d. Review of the 2021 AAB Bacteriology Event #1 PT evaluation form showed no evidence the laboratory director had evaluated the results. e. Review of the 2021 AAB Bacteriology Event #2 PT evaluation form showed no evidence the laboratory director had evaluated the results. 2. Interview with the laboratory manager on 5/9/22 at 1:50 PM revealed she was new to the position and was unaware of the regulation. The laboratory director was unavailable. .
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 review of the CMS-116 form, lack of documentation and staff interview, the laboratory failed to have a written procedure for reporting SARS-CoV-2 positive and negative test results. The laboratory performed approximately 150 SARS-CoV-2 patient tests using a molecular platform and approximately 1,200 patient tests using antigen testing methods annually. The findings were: 1. Review of the CMS-116 form

	showed the laboratory performed molecular testing for SARS-CoV-2 using the Abbott ID NOW COVID-19 and the Biofire Diagnostics Respiratory Panel EZ testing methods. SARS-CoV-2 antigen testing included the BD Veritor System and the Quidel QuickVue testing methods. 2. Review of the laboratory's procedure manuals showed no evidence the laboratory had developed a policy and procedure for reporting SARS-CoV-2 positive and negative test results to the appropriate agencies. 3. Interview with the laboratory manager on 5/9/22 at 3 PM confirmed the laboratory did not have a written procedure for reporting positive and negative SARS-CoV-2 patient 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, the UriCult instructions for use, review of the laboratory's policy and procedure, and staff interview, the laboratory failed to follow the manufacturer's instructions on the incubation time required before reporting patient results for 7 of 7 patient tests reviewed. The laboratory performed 74 UriCult patient tests from 1/7/21 through 5/4/22. The findings were: 1. Review of the medical record for patient #1 showed the urine sample was collected on 2/19/21 at 11:46 AM and "no growth" was reported on 2/25/21 (144 hours). Review of the patient testing log sheet failed to document the time and date the culture result was finalized. 2. Review of the medical record for patient #2 showed the urine sample was collected on 11/8/21 at 3:42 PM and "no growth" was reported on 11/11/21 (72 hours). Review of the patient testing log sheet failed to document the time and date the culture result was finalized. 3. Review of the medical record for patient #3 showed the urine sample was collected on 12/14/21 at 10:20 AM and "growth" was reported on 12/16/21 (48 hours). Review of the patient testing log sheet failed to document the time and date the culture result was finalized. 4. Review of the medical record for patient #4 showed the urine sample was collected on 12/15/21 and "no growth" was reported on 1/6/22 (22 days). Review of the patient testing log sheet failed to document the time and date the culture result was finalized. 5. Review of the medical record for patient #5 showed the urine sample was collected on 1/17/22 and "no growth" was reported on 1/31/22 (14 days). Review of the patient testing log sheet failed to document the time and date the culture result was finalized. 6. Review of the medical record for patient #6 showed the urine sample was collected on 7/22/21 and "no growth" was reported on 7/27/21 (5 days). Review of the patient testing log sheet failed to document the time and date the culture result was finalized. 7. Review of the medical record for patient #7 showed the urine sample was collected on 12/27/21 and "no growth" was reported on 1/3/22 (7 days). Review of the patient testing log sheet failed to document the time and date the culture result was finalized. 8. Review of the UriCult instructions for use showed the UriCult should be incubated for 18 to 24 hours. Incubation should not exceed 24 hours. Incubation exceeding 24 hours may cause bacterial overgrowth resulting in difficult interpretation of colony counts and possibly misleading biochemical reactions. Negative cultures may be incubated for an additional 24 hour period, if desired. This will allow for the detection of slow growing bacteria. 9. Review of the

	laboratory's policy and procedure last revised 9/8/21 showed "Nurse or provider will read UriCult for growth between 18-24 hours. Negative results may be incubated for another 24 hours per UriCult protocol." 10. Interview with the laboratory manager on 5/9/22 at 1:50 PM revealed the urine cultures were incubated for 48 hours before being examined for growth or no growth. In addition, the laboratory manager stated if a culture was started on a Friday it was not read until Monday. The laboratory manager confirmed the patient testing log failed to document the time and date the result of the culture was finalized. .
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on medical record review, billing log review, lack of documentation, and staff interview, the laboratory failed to ensure an adequate system was in place to ensure test results were entered accurately into the final report destination for 8 of 13 urine microscopy patient samples (#1, #2, #5, #8, #9, #10, #11, #12) reviewed from 2/19/21 through 4/22/22. The findings were: 1. Review of the laboratory's billing log showed a urine microscopy had been ordered, however there was no documentation the results had been entered into the electronic medical record for the following patients: a. Patient #1 on 2/19/21. b. Patient #2 on 11/8/21. c. Patient #5 on 1/17/22. d. Patient #8 on 1/14/22. e. Patient #9 on 3/15/22. f. Patient #10 on 4/20/22. g. Patient #11 on 4/21 /22. h. Patient #12 on 4/22/22. 2. The laboratory did not maintain a written record of the urine microscopy results. 3. Interview with the laboratory manager on 5/9/22 at 4 PM confirmed the results of the urine microscopy results were unavailable. .
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: . Based on medical record review, review of the billing log, policy and procedure review, and staff interview, the laboratory failed to follow the written policy and procedure to identify and correct problems in the postanalytical system. The laboratory performed approximately 10 urine microscopy examinations per year. The findings were: 1. Review of the laboratory's billing log showed a urine microscopy had been ordered, however there was no documentation the results had been entered into the electronic medical record for the following patients: a. Patient #1 on 2/19/21. b. Patient #2 on 11/8/21. c. Patient #5 on 1/17/22. d. Patient #8 on 1/14/22. e. Patient

	#9 on 3/15/22. f. Patient #10 on 4/20/22. g. Patient #11 on 4/21/22. h. Patient #12 on 4 /22/22. 2. Review of the Post Analytic Systems policy and procedure last revised 9/06 showed "...5. Lab staff or provider will randomly screen results to see if final result posted, either when pt returns for follow-up visit or at random." 3. There was no evidence the laboratory had an ongoing system to monitor, assess and correct problems in the postanalytical system. 4. Interview with the laboratory manager on 5/9 /22 at 4 PM revealed she was new to the position and was unaware of any quality assurance documentation. The laboratory director was unavailable. .
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: . 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, review of the laboratory's policy and procedure, review of proficiency testing records, review of the CASPER Report 0155, review of the billing log, lack of documentation, and staff interview, the laboratory director failed to ensure testing personnel followed the manufacturer's instructions (D6014), failed to ensure proficiency testing samples were tested in the same manner as patients' specimens (D2000), failed to ensure proficiency testing events were returned within the specified timeframe established by the proficiency testing program (D6017), and failed to ensure the quality assessment program was maintained to assure the quality of laboratory services (D5891). .
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, review of the laboratory's policy and procedure, 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 approximately 48 urine cultures per year. Refer to D5411. .
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that 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, review of the patient test log sheet, and staff interview, the laboratory director failed to ensure testing personnel who routinely perform patient testing participated in the proficiency testing events, failed to ensure testing personnel signed the attestation statement, and failed to maintain a copy of the proficiency testing results. Refer to D2007, D2009, and D2015. .
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: . Based on review of the CASPER Report 0155D and staff interview, the laboratory director failed to ensure the results of 1 of 7 AAB (American Association of Bioanalysts) proficiency testing events (2021 Event #3) was returned within the specified timeframe established by the proficiency testing program. The findings were: 1. Review of Casper Report 0155D showed the laboratory scored a 0% on the AAB 2021 Bacteriology testing Event #3 for lack of participation. 2. Interview with the laboratory manager on 5/9/22 at 1:50 PM revealed she was new to the position and was unaware of the reason the laboratory failed to participate in the AAB 2021 Bacteriology testing Event #3. The laboratory director was unavailable. .
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 medical record review, review of the billing log, policy and procedure review, and staff interview, the laboratory director failed to ensure the quality assessment program was maintained to assure the quality of laboratory services. The laboratory performed approximately 10 urine microscopy examinations per year. Refer to D5891. .

D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on review of the "Competency Assessment" policy, review of the CMS-209 Laboratory Personnel Report form, lack of documentation, and staff interview, the technical consultant failed to ensure competency assessments were completed to ensure physicians and mid-level testing personnel that performed moderate complexity testing were evaluated for competency to process specimens, perform test procedures, and report test results promptly and proficiently. Four mid-level providers (PA (physician assistant) #1, PA #2, NP (nurse practitioner) #1, NP #2) and 3 physicians (MD #1, MD #2, MD #3) performed UriCult urine cultures and urine microscopy laboratory testing. The findings were: 1. Review of the CMS-209 Laboratory Personnel Report form showed 7 testing personnel (PA #1, PA #2, NP #1, NP #2, MD #1, MD #2, MD #3) were listed as testing personnel. Interview with the laboratory manager on 5/9/22 at 1:50 PM confirmed the mid-level providers and physicians performed laboratory testing. 2. Review of the laboratory's records showed no documentation competency assessments had been completed prior to patient testing or anytime thereafter for the mid-level providers or the physicians performing moderately complex laboratory testing. 3. Review of the Quality Control Plan dated 8 /1/16 showed a competency assessment was to be performed 6 months and one year after initial training, and then annually thereafter. "Every laboratory technician will demonstrate continued competency to perform all tests in our facility." In addition, physicians, physician assistants and nurse practitioner that interpret urine cultures will receive a peer evaluation, 2 to 4 times annually, and documentation will be kept in the quality assurance notebook, then reviewed and photocopies made and placed in the laboratory book. 4. Interview with the laboratory manager on 5/9/22 at 1:50 PM revealed she was new to the position and was unaware of any further documentation.