Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0663229	06/22/2023
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Casper 155D report, review of the AAB (American Association of Bioanalysts)-Medical Laboratory Evaluation (MLE) reports, and staff interview, the laboratory failed to successfully participate in two consecutive AAB-MLE nonchemistry testing events for the urine culture test system (2022 event #3, 2023 event #1). Refer to D2026.
D2026	BACTERIOLOGY CFR(s): 493.823(d)

	(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) Casper 155D report, review of the American Association of Bioanalysts (AAB)-Medical Laboratory Evaluation (MLE) evaluation reports, and staff interview, the laboratory failed to sucessfully participate in two consecutive AAB-MLE nonchemistry proficiency testing (PT) events for the urine culture test system (2022 event #3, 2023 event #1). The findings were: 1. Review of the CMS Casper 155D report and the AAB-MLE nonchemistry PT evaluations showed the laboratory failed to sucessfully obtain a passing score for the urine culture test system on the following testing events: a. 2022 event #3 showed the laboratory scored a 40%. b. 2023 event #1 showed the laboratory scored a 60%. 2. Telephone interview with the laboratory manager on 6/12 /23 at 3:29 PM revealed education was provided to staff after the failed PT event in 2022; however, she was unaware the first event of 2023 had failed to achieve a passing score as the laboratory had not received the results of the PT event. 3. Telephone interview with the laboratory director on 6/22/23 at 10:25 AM confirmed the laboratory had failed two consecutive proficiency testing events.
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 review of the Centers for Medicare and Medicaid Services Casper 155D report, review of the American Association of Bioanalysts (AAB)-Medical Laboratory Evaluation (MLE) proficiency testing reports, and staff interview, the laboratory director failed to ensure an effective corrective action plan was developed to prevent reoccurrence of the failed urine culture test system for 2 consecutive AAB-MLE nonchemistry proficiency testing events (2022 event #3, 2023 event #1). Refer to D6019.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

	This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Casper 155D report, review of the American Association of Bioanalysts (AAB)-Medical Laboratory Evaluation (MLE) reports, and staff interview, the laboratory director failed to ensure an effective corrective action plan was developed to prevent reoccurrence of the failed urine culture test system for 2 consecutive AAB-MLE nonchemistry proficiency testing events (2022 event #3, 2023 event #1). Refer to D2026.