

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0519862	(X3) Date Survey Completed 09/26/2024
Name of Provider or Supplier So Big Horn Co Hospital	Street Address, City, State 388 Us Hwy 20 South, Basin, 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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>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 have a system in place for reviewing proficiency testing results that received an artificial score of 100% for 8 of 29 American Proficiency Institute (API) proficiency testing events reviewed from September 2022 through August 2024. The findings were: 1. Review of the 2022 API Microbiology Event #3 proficiency testing evaluation showed sample UR-11 (urine culture MIC /zone diameter value) was not graded and the laboratory was directed to view the data summary. There was no evidence the non-graded proficiency testing sample had been evaluated. 2. Review of the 2023 API Chemistry Core Event #1 proficiency testing evaluation showed the laboratory received an artificial score of 100% on sample CH-01 (alanine transaminase) due to a lack of consensus. There was no evidence the non-graded proficiency testing sample had been evaluated. 3. Review of the 2023 API Microbiology Event #1 proficiency testing evaluation showed sample UR-01 (urine culture MIC/zone diameter and susceptibility interpretation for ceftazidime) was not graded and the laboratory was directed to view the data summary. There was no evidence the non-graded proficiency testing sample had been evaluated. 4. Review of the 2023 API Microbiology Event #2 proficiency testing evaluation showed sample BL-01 (blood culture MIC/zone diameter value) and sample UR-06 (urine culture MIC /zone diameter value) were not graded and the laboratory was directed to view the data summary. There was no evidence the non-graded proficiency testing sample had</p>

been evaluated. 5. Review of the 2023 API Microbiology Event #3 proficiency testing evaluation showed sample UR-11 (urine culture MIC/zone diameter value) was not graded and the laboratory was directed to view the data summary. There was no evidence the non-graded proficiency testing sample had been evaluated. 6. Review of the 2024 API Chemistry Core Event #1 proficiency testing evaluation showed samples CH-02, CH-03, and CH-05 (total bilirubin) were not graded due to "results variance". Samples CH-01, CH-02, CH-03, CH-04, and CH-05 (lipase) were not graded and the laboratory was directed to view the data summary. There was no evidence the non-graded proficiency testing samples had been evaluated. 7. Review of the 2024 API Microbiology Event #1 proficiency testing evaluation showed sample SF-01 (cerebrospinal fluid MIC/zone diameter) was not graded and the laboratory was directed to view the data summary. Sample GS-02 (gram stain morphology) and sample UR-01 (urine culture MIC/zone diameter value and susceptibility interpretation for trimethoprim/sulfamethoxazole) were not graded. There was no evidence the non-graded proficiency testing sample had been evaluated. 8. Review of the 2024 Microbiology Event #2 proficiency testing evaluation showed sample UR-06 (urine culture MIC/zone diameter and susceptibility interpretation for ciprofloxacin and gentamicin) were not graded. There was no evidence the non-graded proficiency testing sample had been evaluated. 9. Interview with the general supervisor on 9/26/24 at 10:02 AM revealed he reviewed the non-graded proficiency testing samples; however, he did not document the results of his evaluation.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:
Based on review of proficiency testing records, policy and procedure review, and staff interview, the laboratory failed to at least twice annually verify the accuracy of ammonia for 1 of 2 years (2023) reviewed. The laboratory performed approximately 14 ammonia patient tests per year. The findings were: 1. Review of the American Proficiency Institute proficiency testing records showed the laboratory scored a 100% on the 2023 Chemistry Miscellaneous Event #1 for ammonia. Further review showed the laboratory scored 67% on ammonia on Event #2 of 2023. A corrective action plan was implemented; however, the laboratory failed to verify the effectiveness of the corrective action. 2. Interview with the general supervisor on 9/26/24 at 10:02 AM confirmed the accuracy of the ammonia assay had not been verified as required. 3. Review of the policy "LAB-3018-33 Proficiency Testing", effective 2/2/24, showed "...14. Any analyte receiving a score that does not accurately reflect the actual performance will be verified for accuracy by either self-grading using the PT data, or split specimen analysis..."