

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0519856	(X3) Date Survey Completed 08/28/2024
Name of Provider or Supplier Cody Regional Health Dbawest Park Co Hospital	Street Address, City, State 707 Sheridan Ave, Cody, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>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 process for 2 of 29 (2022 Immunology/Immunochemistry event #2, Immunology/Immunochemistry event #3) American Proficiency Institute (API) proficiency testing events reviewed from September 2022 through August 2024. The findings were: 1. Review of the laboratory's proficiency testing records showed no evidence of the performance summary, the comparative evaluations, or the signed performance reviews which indicated the results had been reviewed by the laboratory director for the 2022 Immunology/Immunochemistry event #2 and event #3. 2. Interview with the laboratory manager on 8/28/24 at 11:22 AM confirmed no further documentation was available.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p>

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on review of the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, review of personnel records, policy and procedure review, and staff interview, the laboratory failed to ensure 5 of 5 laboratory personnel (LP #1, LP #2, LP #3, LP #4, LP #5) technical supervisor and/or general supervisor's competency assessments were completed for 2 of 2 years (2022, 2023) reviewed. The findings were: 1. Review of the CMS 209 Laboratory Personnel Report showed the laboratory employed 4 technical supervisors and 4 general supervisors. The following concerns were identified: a. LP #1 performed the duties of the technical and general supervisor for Diagnostic Immunology and Hematology. Review of the personnel files for LP #1 showed no evidence a competency assessment had been completed in 2022 or 2023. b. LP #2 performed the duties of the technical supervisor for Chemistry. Review of the personnel files for LP #2 showed no evidence a competency assessment had been completed in 2022 or 2023. c. LP #3 performed the duties of the general supervisor in Chemistry. Review of the personnel files for LP #3 showed no evidence a competency assessment had been completed in 2022 or 2023. d. LP #4 performed the duties of the technical supervisor for Microbiology (bacteriology, mycology, parasitology, virology) and the general supervisor duties for Immunochemistry. Review of the personnel files for LP #4 showed no evidence a competency assessment had been completed in 2022 or 2023. e. LP #5 performed the duties of the technical consultant and general supervisor for Chemistry. Review of the personnel files for LP #5 showed no evidence a competency assessment had been completed in 2022 or 2023. 2. Review of the policy titled "Laboratory Orientation and Competency", last revised and approved by the laboratory director on 1/31/20, failed to include a procedure for ensuring the competency of the technical and general supervisors. 3. Interview with the laboratory manager on 8/27/24 at 3 PM confirmed the competency assessments had not been completed for the technical and general supervisors and the policy and procedure was incomplete.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on policy and procedure review and staff interview, the laboratory director failed to specify, in writing, the responsibilities and duties of the general and technical supervisors. The findings were: 1. Review of the "Lab Personnel Duties" policy, last revised and signed by the laboratory director on 1/31/20, showed the duties and responsibilities of the "Section Heads" were outlined; however, there was no delineation between the duties of the technical supervisor and the general supervisor.

2. Interview with the laboratory manager on 8/27/24 at 3 PM confirmed the policy did not define the specific duties of the general supervisor and technical supervisor.