

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D0518570	(X3) Date Survey Completed 09/30/2024
Name of Provider or Supplier Valley Citizens' Foundation For Health Care Inc	Street Address, City, State 310 County Rd 14, Del Norte, CO	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel files, policies and procedures manual, and an interview with the laboratory's general supervisor (GS), the laboratory failed to assess the competency of testing personnel (TP) after their initial competency but within their first 6 months of employment; assess or establish a written policy or procedure for assessing the competency of personnel in the position of technical supervisor (TS), and GS. The laboratory conducts approximately 303,659 tests annually. Findings include: 1. A review of the laboratory's personnel files revealed the laboratory was assessing initial and annual competency for TP, but not assessing competency at least 6 months after initial competency was assessed in TP first year of employment since the last survey was conducted on September 24, 2021. 2. A review of the laboratory's personnel files, and policies and procedures manual revealed that the laboratory failed to assess the competency of, or establish a written policy or procedure for assessing the competency for one out of one TS, and one out of one GS listed on the CMS-209 Form since the last survey was conducted on September 24, 2021. 3. Based on an interview with the GS, on September 30, 2024, at approximately 11:00 AM, confirmed that the laboratory failed to assess the competency of TP within 6 months of completing their initial competencies, and failed to assess the competency of, or establish a written policy or procedure to assess the competency of personnel in the positions of TS, and GS.</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p>

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on an onsite records review, a review of the laboratory's policies and procedures manual, and an interview with the general supervisor (GS), the laboratory failed to compare, or establish a policy or procedure to compare their Cepheid SARS-CoV-2 multiplex assay to their Biofire respiratory panel at least semiannually, and failed to compare their Sysmex Hematology analyzer's automated white blood cell (WBC) differential at least semiannually to their manual WBC differential since the laboratory's last survey on September 24, 2021. The laboratory conducts approximately 4,665 microbiology tests, and 80,830 hematology tests annually. Findings include: 1. Based on an onsite records review, the laboratory failed to compare the Cepheid SARS-CoV-2 multiplex assay to the Biofire respiratory panel at least semiannually. 2. Based on an onsite records review, the laboratory failed to compare the automated WBC differential obtained on their Sysmex Hematology analyzer to the results obtained using manual WBC differentials at least semiannually. 3. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish a policy or procedure to compare the Cepheid SARS-CoV-2 multiplex assay to the Biofire respiratory panel, and automated WBC differential obtained on their Sysmex Hematology analyzer to the results obtained using manual WBC differentials at least semiannually. 4. Based on an interview with the GS on September 30, 2024, at approximately 2:25 PM, confirmed that the laboratory failed to compare and establish a policy or procedure to compare the Cepheid SARS-CoV-2 multiplex assay to their Biofire respiratory panel, and their automated WBC differential obtained on their Sysmex Hematology analyzer to the results obtained using manual WBC differentials at least semiannually.