

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0681667	(X3) Date Survey Completed 01/20/2022
Name of Provider or Supplier Powell Valley Healthcare	Street Address, City, State 777 Avenue H, Powell, 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the new instrumentation and new test methodology verification studies, policy and procedure review, and staff interview, the laboratory failed to verify precision prior to testing patient samples for 2 of 4 new instrument and/or test methodology verification studies reviewed (Sysmex XN-550, Alcor miniiSED). The laboratory performed approximately 72,000 hematology tests annually and 130 erythrocyte sedimentation rates from 8/30/21 through 1/20/22. The findings were: 1. Review of the Sysmex XN-550 new instrument verification study completed on 1/25/21 showed an analysis of the performance specification of precision had not been performed prior to testing patient samples. 2. Review of the Alcor miniiSED new test methodology verification study completed on 8/30/21 showed the performance specification of precision had not been verified. In addition there was no evidence the laboratory director had reviewed the verification study documentation and approved the test procedure prior to testing patient samples. 3. Interview with the technical consultant on 1/20/22 at 12:15 PM confirmed the verification studies were incomplete. 4. Review of the "New Test, Method or Instrument Procedure" reviewed by the laboratory director on 1/18/22 showed "...When adding or replacing a test, method or instrument, PVHC laboratory shall verify the manufacturer's performance specifications regarding accuracy, precision and reportable ranges."</p>

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on review of the Sysmex XN-550 new instrument and the Alcor miniSED new test method verification documentation, policy and procedure review, and staff interview, the laboratory director failed to ensure the test verifications of accuracy, precision, analytic specificity, and analytic sensitivity was complete and met the laboratory's performance characteristics specified by the manufacturer. Refer to D5421.