

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0925425	(X3) Date Survey Completed 02/01/2019
Name of Provider or Supplier Banner Health Physicians West Llc	Street Address, City, State 1020 S Conwell, Casper, 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
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on complete blood count quality control records review, lack of documentation, and interview with staff, the laboratory failed to monitor quality control (QC) accuracy and precision performance over time to detect issues such as test system failure, changes in environmental conditions, and operator performance for complete blood count (CBC) testing performed from the tests beginning in July 2017 to the day of survey. The laboratory performed approximately 4200 CBC tests per year. Finding include: 1. Laboratory quality control records review failed to include documentation the laboratory monitored quality control results performance over time. 2. The laboratory failed to document quality control results were plotted against the determined tests statistical mean and standard deviation through Levy Jennings (L/J) graphs or other statistical monitoring methods for identification of accuracy and precision issues and of test results shifts and/or trends. 3. In an interview conducted on 02/01/2019 at approximately 2:00 P.M., staff stated they did not have a method to</p>

evaluate quality control performance over time to monitor shifts and trends in results that are not observed from daily QC testing. The laboratory CBC instrument includes the option to print L/J graphs for QC monitoring features.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on patient test records review, lack of documentation, and interview with staff, the laboratory failed to ensure maintenance of a record system that included the identity of the personnel who performed complete blood count (CBC) testing reviewed from October 2017 to January 2019 for 5 of 5 testing personnel. The laboratory performed approximately 4200 CBC tests per year. Findings include: 1. Patient test records review included the handwritten initials of the testing personnel performing CBC tests on instrument printouts as the laboratory method to identify testing personnel. 2. The laboratory failed to document the identity of the personnel to whom the handwritten initials matched. 3. In an interview with staff on 02/01/2019 at approximately 1:45 P. M., staff confirmed they did not have a system to record the testing personnel's initials with a direct link to the testing person's name. Staff stated two of the testing personnel who initialed CBC test results for patient number H68818 tested on 10/19/2017 and patient number F61380 tested on 01/26/2018 included initials for an employee who no longer worked in the laboratory. The initials were identified by current testing personnel who worked with the testing personnel present in 2017 and early 2018.