

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2099145	(X3) Date Survey Completed 02/15/2024
Name of Provider or Supplier Banner Health Physicians West Llc	Street Address, City, State 3632 American Way, 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
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to verify the statistical parameters of quality control material prior to use for 1 of 1 test system (Hematology) reviewed. The findings were: 1. There was no documentation the laboratory had verified new lot numbers of quality control material prior to being used on the Sysmex Poch-100i analyzer. 2. Interview with technical consultant #1 and technical consultant #2 on 2/16/24 at 11:01 AM confirmed the statistical parameters of the quality control materials had not been verified.</p>