Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0041965	05/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
Big Horn Hospital Association	17 North Miles Avenue, Hardin, MT	

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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a record review, procedure, and an interview with the technical supervisor (TS) #1, the laboratory failed to ensure reagents were not used past their expiration date for 18 of 18 patients tested with Helicobacter Pylori (H Pylori) kits and 15 of 15 patients tested with Rubella kits from May 2, 2022 to April 20, 2023. Findings: 1. A review of H. Pylori log-in sheet revealed the laboratory used expired kits to perform patient testing on eleven patients from 6-9-22 to 10-4-22 using lot# 241B11 exp 5-31-2022 and seven patients from 4-11-23 to 4-20-23 using lot# 241L11 exp 2-28-2023. 2. A review of the Rubella log-in sheet revealed the laboratory used expired kits to perform patient testing on three patients from 5-2-22 to 6-6-22 using lot# B33782 exp 4-14-22 and 12 patients from 2-1-23 to 4-6-23 using lot# 1M22G3 exp 1-31-23. 3. A review of H. pylori's and Rubella's individualized quality control plan (IQCP) revealed the laboratory lacked instruction to not use expired kits. 4. An interview on May 31, 2023, at 10:00 a.m. with TS #1 confirmed the laboratory failed to ensure H. pylori and Rubella kits were not used past their expiration dates for 33 patients tested from May 2, 2022, to April 20, 2023.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of coagulation records, procedures, and interview with technical supervisor (TS) #1, the laboratory failed to verify new lots of Activated Partial Thrombin Time (aPTT) reagents performed on the STA Satellite normal values from May 31, 2021, to May 31, 2023. Findings: 1. A review of "Partial Thromboplastin Time, aPTT-STA Satellite" procedure revealed the laboratory failed to have a step-by-step procedure for verifying new lots of reagents. 2. No rollover studies containing a calculated geometric mean, standard deviation and reference range check for new lots of aPTT reagents were available for review. 3. A review of the test volume sheet revealed 211 aPTT tests were resulted from May 23, 2022, to May 23, 2023 (12-month period). 4. An interview with the TS #1 on May 31, 2023, at 4:53 PM, confirmed the laboratory failed to verify new lots of reagents for aPTT from May 31, 2021, to May 31, 2023.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation, review of maintenance records and interview with technical supervisor (TS) #1, the laboratory failed to recertify one of one Biosafety Cabinet located in the Microbiology Section from May 31, 2021 to May 31, 2023. Findings: 1. Observed one Microbiology Biosafety Cabinet with a certification sticker that had expired in 2021. 2. No certification or maintenance records for the Biosafety Cabinet were available for review from May 31, 2021 to May 31, 2023. 3. An interview on May 31, 2023 at 8:30 AM with (TS) #1, confirmed the Biosafety Cabinet certification had expired in 2021.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) 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.

	This STANDARD is not met as evidenced by: Based on review of chemistry quality control (QC) records, procedures, manuals, and interview with the Technical Supervisor (TS) #1, the laboratory failed to establish acceptable criteria (mean and standard deviation) for new lots of Bio-Rad liquid unassayed multiqual controls performed on the Ortho VITROS 5600 chemistry analyzer from May 31, 2021, to May 31, 2023. Findings: 1. The laboratory failed to follow the manufacturer's Statistical Tools of Quality Control: Training Module as stated, "The mean must be calculated or evaluated before a new lot number of quality-control material is used because each lot number has its own concentration of the analyte.", and "For VITROS Systems, you should re-evaluate means when new lot numbers of slides, VITROS Reference Fluid, or Immuno-Wash Fluid are put into use." 2. No correlations studies for new lots of quality control materials to establish statistical limits for the Ortho VITROS 5600 chemistry analyzer were available for review. 3. No studies for re-evaluating the mean for new lots of VITROS reagents (slides, Reference Fluid, or Immuno-Wash Fluid) were available for review. 4. Chemistry procedures lacked instructions for evaluating new lots of QC and new lots of reagents. 5. A review of the test volume sheet revealed 63,484 chemistry results were reported from May 23, 2022, to May 23, 2023 (12-month period). 6. An interview with (TS) #1 on May 31, 2023, at 3:00 PM, confirmed the laboratory failed to establish acceptable QC statistical parameters for each analyte tested on the Ortho VITROS 5600 chemistry analyzer from May 31, 2021, to May 31, 2023.