Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0671192	05/01/2025
Name of Provider or Supplier	**Street Address, City, State**	
Clark Fork Valley Hospital	10 Krueger Road, Plains, 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
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a record review of microbiology, and the laboratory's procedure, the laboratory failed to have a step-by-step protocol for the VITEK and a microbiology quality control procedure (refer to D5403); failed to follow the manufacturer's package insert to ensure microbiology quality control swabs were not used past their expiration date (refer to D5417); failed to establish an Individualized Quality Control Plan (IQCP) for BACT/ALERT Culture Media bottles (refer to D5445); failed to perform quality checks (QC) for sterility and the ability to support growth for each new lot or shipment of chocolate media (refer to D5477); and failed to include in their test records the number, type of media and actual observations of the results for each microbiology media used for patient testing (refer to D5787).
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a record review of hematology, and the laboratory's procedure, the laboratory failed to have a procedure for the Sysmex CA-660 coagulation instrument

	rollover studies of new reagent lots with new quality control lots (refer to D5403); failed to follow the manufacturer's instructions to update the update the Sysmex CA-660 coagulation instrument with the new lot of Dade Innovin Reagent's International Sensitivity Index (ISI) value and failed to calculate the mean normal prothrombin time (refer to D5411).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of microbiology and hematology procedures, and an interview with the General Supervisor (GS) #1, the laboratory failed to include a step-by-step protocol for the VITEK, a quality control procedure for microbiology, and a procedure for rollover studies of new reagent lots with new quality control lots performed on the Sysmex CA-660 coagulation instrument from April 30, 2023, to April 30, 2025. Findings: 1. The laboratory failed to provide the following procedures: a. A step-by-step performance of the procedure, interpretation of results and reporting requirements for the VITEK. b. A microbiology quality control procedure to include the type and identity of control organism, how to perform sterility testing, criteria to determine acceptable control results, and corrective actions to take when QC is not acceptable. c. A procedure for maintaining microbiology quality control stock and working cultures. d. A Sysmex CA-660 coagulation instrument procedure for rollover studies of new reagent lots with new quality control lots. 2. An interview with GS #1 on April 30, 2025, at 4:40 PM, confirmed procedures lacked a step-by-step protocol for the VITEK, a quality control procedure for microbiology and a procedure for coagulation rollover studies of new reagent lots with new quality control lots from April 30, 2023, to April 30, 2025.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results

	within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a record review, observation, and an interview with the General Supervisor (GS) #1, the laboratory failed to follow the manufacturer's instructions to update the Sysmex CA-660 coagulation instrument with the current lot of Dade Innovin Reagent's International Sensitivity Index (ISI) value, and verify the mean normal prothrombin time (MNPT) used to calculate the International Normalized Ratio (INR) from April 30, 2023, to April 30, 2025. Findings: 1. An observation of one Sysmex CA-660 coagulation instrument in the laboratory on April 30, 2025, at 1:45 PM noted the following values entered: Dade Innovin lot #564615, expiration date 03/03/25, International Sensitivity Index (ISI) value of 1.04 and MNPT of 10.0 seconds. 2. A review of the current (in use) Dade Innovin reagent's product insert revealed a different lot #564652 with an expiration date of 08/04/25 that had an ISI value of 1.06. No start date was recorded. 3. The laboratory lacked documentation of the laboratory's calculated mean normal prothrombin time (MNPT) for its patient population, as required by the manufacturer's instructions since the verification study of the Sysmex CA-660 instrument on 12/28/2022. 4. A review of the test volume sheet revealed 488 prothrombin time patient tests were performed in the last 12 months, from April 30, 2024, to April 30, 2025. 5. An interview with GS #1 on April 30, 2025, at 2:00 PM confirmed the information on the Sysmex CA-660 coagulation instrument had not been updated with the current lot of Innovin reagent, and the laboratory failed to calculate the MNPT value from April 30, 2023, to April 30, 2025.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observations, review of the manufacturer's product insert, and an interview with the General Supervisor (GS) #1, the laboratory failed to label 10 of 10 sets of chemistry and immunoassay quality control (QC) material, once opened, with the open-vial stability expiration date from April 30, 2023, to April 30, 2025. Findings: 1. Observed on April 30, 2025, at 4:00 PM, one tray containing 10 sets of quality control for the Siemens Dimension EXL chemistry analyzer was in use in the refrigerator. The quality control labels lacked the open-vial stability expiration date. 2. A review of Bio-Rad's product inserts revealed the laboratory failed to label its quality control vials with the manufacturer's stability expiration date for the following sets of QC: Liquichek Spinal Fluid, Lyphochek Specialty Immunoassay, Liquichek Ethanol /Ammonia, Liquichek Diabetes, Liquichek Cardiac Troponins, Liquichek Cardiac Markers Plus, Liquichek Urine Chemistry, Liquichek Immunoassay Plus, and Liquid Unassayed Multiqual. 3. Interview with GS #1 on April 30, 2025, at 4:10 PM, confirmed that 10 of 10 sets of QC vials lacked the stability expiration date after the vial was opened to prevent QC from being used past the manufacturer's recommended stability of their product from March 18, 2023, to March 19, 2025.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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, manufacturer's package insert, and an interview with Technical Supervisor (TS) #2, the laboratory failed to follow the manufacturer's package insert to ensure 21 of 23 microbiology American Type Culture Collection (ATCC) quality control swabs were not used past their expiration date from April 30, 2023, to April 30, 2025. Findings: 1. A review of the "Stock Cultures" log listed 23 different ATCC quality control organisms used to perform quality checks of media, stains, reagents and identification kits. The log lacked documentation of lot number, expiration date, and dates of the working culture. 2. A review of four ATCC quality controls in inventory revealed that the laboratory failed to follow the Remel Culti-Loop package insert, which states not to use its product past the expiration date from April 30, 2023, to April 30, 2025. Culti-Loops Stenotrophomonas maltophilia ATCC 17666 with an expiration date of 7/31/2009; Culti-Loops Proteus vulgaris ATCC 6380 with an expiration date of 7/31/2009; Culti-Loops Klebsiella quasipneumoniae subsp. pneumoniae ATCC 700603 with an expiration date of 3/31/2009; Culti-Loops Enterococcus casseliflavus ATCC 700327 with an expiration date of 5/31/2009. 3. An interview with TS #2 on April 30, 2025, at 9:20 AM stated that 21 of 23 ATCC quality controls were expired from April 30, 2023, to April 30, 2025. 4. A review of the test volume sheet revealed that 1591 patient cultures were performed in the last 12 months, from April 30, 2024, to April 30, 2025.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, procedures, and interviews with Technical Supervisor (TS) #2 and General Supervisor (GS) #1, the laboratory failed to (A) establish an Individualized Quality Control Plan (IQCP) for BACT/ALERT Culture Media bottles from April 30, 2023, to April 30, 2025; and (B) failed to perform monthly external quality control for seven out of twelve months, as required by their Individualized Quality Control Plan (IQCP) from April 30, 2024, to April 30, 2025. Findings: A. BACT/ALERT 1. A review of microbiology QC records revealed that the laboratory was using the manufacturer's Certificate of Conformance for each new lot of BACT/ALERT Culture Media. The QC records lacked documentation of

	sterility and the ability to support growth for each new lot or shipment. 2. There was no IQCP evaluation containing a risk assessment, a quality control plan, and a quality assessment plan to support the QC practices that are less stringent than the regulatory control requirements for the BACT/ALERT culture media. 3. A review of the test volume sheet revealed the laboratory reported 681 blood culture results from April 30, 2023, to April 30, 2025 (12-month period). 4. An interview with TS #2 on April 30, 2025, at 10:55 AM confirmed that the laboratory failed to establish an IQCP for alternative QC practices for the BACT/ALERT Culture Media from April 30, 2023, to April 30, 2025. B. EPOC 1. A review of the epoc QC records revealed that the laboratory failed to perform two levels of external QC monthly as required by their IQCP for June, July, August, October, November, and December of 2024, as well as March 2025. 2. An interview with GS #1 on April 30, 2025, at 4:25 PM confirmed that the laboratory failed to perform two levels of external QC monthly for seven out of twelve months, as required by their IQCP from April 30, 2024, to April 30, 2025.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. This STANDARD is not met as evidenced by: Based on a record review and an interview with Technical Supervisor (TS) #2, the laboratory failed to perform quality checks (QC) for sterility and the ability to support growth for each new lot or shipment of chocolate media from April 30, 2023, to April 30, 2025. Findings: 1. A review of the "Bacteriology QC/QA" and "Media Quality Control" logs lacked documentation of media QC to support growth and sterility for each new lot or shipment of chocolate media. 2. A review of microbiology's Individualized Quality Control Plan (IQCP) for "Commercially Prepared CLIS-Exempt Media" did not include chocolate media. 3. An interview with TS #2 on April 30, 2025, at 9:30 AM confirmed that the laboratory failed to perform quality checks (QC) for sterility and the ability to support growth for each new lot or shipment of chocolate media from April 30, 2023, to April 30, 2025.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, policies, and interview with general supervisor (GS #1), the laboratory failed to perform corrective action for missed

	external quality control checks to ensure patients tested and results reported with the Siemens epoc blood analysis system were not adversely affected from April 30, 2023, to April 30, 2025. Findings: 1. There were no records of corrective actions for the missed monthly external QC checks of epoc's blood analysis for blood gases (pCO2 (partial pressure of carbon dioxide), pO2 (partial pressure of oxygen) and pH), electrolytes (sodium, potassium, ionized calcium, and chloride), lactate, glucose, creatinine and hematocrit. (Cross Refer D5445) 2. There were no assessments of patients' test results to ensure patients were not adversely affected since the last acceptable external quality control for review. 3. An interview with GS #1 on April 30, 2025, at 12:00 PM confirmed the lack of corrective action for the epoc's missed external QC to ensure patients tested and reported were not adversely affected from April 30, 2023, to April 30, 2025.
D5787	TEST RECORDS CFR(s): 493.1283(a) (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 record review, and interview with technical supervisor (TS) #2, the laboratory failed to include in their test records the number, type of media and actual observations of the results for each microbiology media used for patient testing from April 30, 2023, to April 30, 2025. Findings: 1. A review of two patients' microbiology test records (230950003MF and 230950014MF) setup on 4/5/2025 failed to include the number and type of media used for patient testing with corresponding observed results. 2. A review of patient test records and microbiology Individualized Quality Control Plan (IQCP) for media indicate the following media available for use: Sheep Blood Agar (SBA), MacConkey agar (MAC), Columbia (CNA) agar, Brucella Agar w/ Hemin/Vit K agar, Mannitol Salt Agar, Hektoen (HE) Agar, LIM Broth, Cefsulodin Irgasan Novobiocin (CIN) Agar, Thioglycolate Broth (THIO), Gram-Negative (GN) Broth, and Chocolate Agar. 3. An interview with TS #2 on April 30, 2025, at 4:30 PM confirmed the laboratory failed to include in their test records the number, type of media and actual observations of the results for each microbiology media used for patient testing from April 30, 2023, to April 30, 2025.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on hematology and microbiology record review and procedures, the laboratory director (LD) #1 failed to ensure that the quality control programs were effectively monitored by laboratory staff to assure the quality of laboratory services provided

	from April 30, 2023, to April 20, 2025. (refer to D5002 and D5024) Findings: 1. The laboratory director failed to ensure staff followed the manufacturer's package insert to ensure microbiology quality control swabs were not used past their expiration date (refer to D5417). 2. The laboratory director failed to establish an Individualized Quality Control Plan (IQCP) for BACT/ALERT Culture Media bottles (refer to D5445). 3. The laboratory director failed to ensure staff perform quality checks (QC) for sterility and the ability to support growth for each new lot or shipment of chocolate media (refer to D5477). 4. The laboratory director failed to ensure lab staff followed the manufacturer's instructions to update the coagulation instrument with the new lot of Dade Innovin Reagent's International Sensitivity Index (ISI) value and perform the calculated mean normal prothrombin time (refer to D5411).