

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0671192	(X3) Date Survey Completed 06/22/2023
Name of Provider or Supplier Clark Fork Valley Hospital	Street Address, City, State 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient results reports, chemistry records, and interview with the General Supervisor (GS) #1, the laboratory failed to retain the quality control (QC) documentation for chemistry analytes performed on the Siemens Dimension EXL chemistry analyzer from June 22, 2021 to December 22, 2022. Findings: 1. Review of seven out of eight patient results reports for Hemoglobin A1c, TSH, Lipid Panel, Total PSA, Phenytoin, Phenobarbital, Comprehensive Metabolic Panel, NT-proBNP, High-sensitivity Troponin I performed on the Siemens Dimension EXL chemistry analyzer from June 22, 2021 to December 22, 2022 lacked QC records. 2. No procedure was available to clarify the two-year requirements for the retention of laboratory data. 3. Interview on June 22, 2023 at 2:40 PM with GS #1 confirmed the QC documentation for the Siemens Dimension EXL chemistry analyzer is not retained past six months (June 22, 2021 to December 22, 2022).</p>
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</p>

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, and interview with the general supervisor (GS) #1, the laboratory failed to establish acceptable criteria (mean and standard deviation) for new lots of BioRad unassayed chemistry controls performed on the Dimension EXL chemistry analyzer from June 22, 2021, to June 22, 2023. Findings: 1. No correlations studies for new lots of BioRad unassayed quality control materials to establish statistical limits for the Dimension EXL chemistry analyzer were available for review. 2. No chemistry procedure for the evaluation of new lots of unassayed quality control and acceptable control limits were available for review. 3. A review of the test volume sheet revealed 146,125 chemistry results were reported from June 22, 2022, to June 22, 2023 (12 months). 4. An interview with GS#1 on June 22, 2023, at 3:00 PM, confirmed the laboratory failed to establish acceptable QC statistical parameters for each analyte tested on the Dimension EXL chemistry analyzer from June 22, 2021, to June 22, 2023.

D5543

HEMATOLOGY

CFR(s): 493.1269(a)(d)

(a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of hematology quality control (QC) records, patient results report, and interview with the general supervisor (GS) #1, the laboratory failed to obtain and perform one control material in duplicate for manual cell counts performed using the hemocytometer from June 22, 2021, to June 22, 2023. Findings: 1. A review of patient results reports (#230400456HF and #230980334HF) for Cell Count, Cerebrospinal Fluid (CFS) dated 2/9/2023 and Cell Count, Body Fluid dated 4/8/2023, revealed the laboratory failed to perform one QC in duplicate the day of testing. 2. Review of Body Fluid and Cerebrospinal Fluid Analysis revealed the laboratory failed to follow their procedure as stated, "Run appropriate quality control on spinal fluid QC material (Liquichek Spinal Fluid Control)." 3. An interview with GS #1 on June 22, 2023, at 4:00 PM, confirmed the laboratory failed to purchase and perform one control material in duplicate for the hemocytometer from June 22, 2021, to June 22, 2023.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain

their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on the review of employees' annual competency files for years 2022 and 2023, the CMS-209 Laboratory Personnel Report, and an interview with the general supervisor (GS) #1, the technical supervisor failed to perform annual competency assessments for two out of eleven testing personnel for the year 2022. Findings: 1. A review of annual competency records for the year 2022 lacked annual competencies for two out of eleven testing personnel (TP-6 and TP-7). 2. The laboratory failed to have a procedure for respiratory therapy defining the six elements required for competency assessment and to include the evaluation and documentation of new testing personnel at least semiannually during the first year of patient testing. 3. Interview with the GS #1 on June 22, 2023, at 9:00 AM, confirmed annual competencies were missed for year 2022 for two out of eleven testing personnel.