

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0409929	(X3) Date Survey Completed 02/15/2023
Name of Provider or Supplier Prairie Community Hospital	Street Address, City, State 312 South Adams, Terry, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with the Laboratory Director (LD) #1, the laboratory failed to enroll in an HHS-approved proficiency testing program for prostate-specific antigen (PSA) from April 5, 2022 to February 15, 2023. Findings: 1. A review of the Test Volume Report revealed 35 PSA tests were performed from February 15, 2022 to February 15, 2023 (12 months). 2. A review of 2022 American Proficiency Institute (API), testing program records lacked documentation of proficiency testing for PSA. 3. An interview on February 15, 2023, at 9:00 AM with the LD#1 confirmed the laboratory failed to enroll in an HHS-approved proficiency testing program for prostate-specific antigen (PSA) from April 5, 2022 to February 15, 2023.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when</p>

appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on observation, policies and procedures, and an interview with Laboratory Director (LD) #1, the laboratory failed to follow their written policies and procedures to label four out of five nasopharyngeal (NP) swabs collected in viral transport media (VTM) with the full name, date of birth, and date and time of collection on February 15, 2023. Findings: 1. Observed five VTM specimen collection tubes containing NP swabs in the laboratory refrigerator on February 15, 2023, in which four out of the five specimen labels lacked date of birth and date and time of collection. 2. A review of "Specimen Collection and Handling" procedure revealed the staff failed to follow their procedures as stated, "V. Obtaining Nasopharyngeal secretions, 7. Label in the presence of the patient with the full name, date of birth and date and time of collection". 3. An interview with the LD #1 on February 15, 2023, at 10:15 AM confirmed these findings.

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, the manufacturer's manual, procedure, and an interview with the Laboratory Director (LD) #1, the laboratory failed to ensure reagents were not used past their expiration date for i-STAT Chem 8+ and CG 4+ cartridges for two to two patients tested on September 15, 2021, and November 14, 2021.. Findings: 1. A review of the iSTAT test cartridge log-in sheet revealed the laboratory used expired cartridges to test patients: One patient tested on 11/14/21 with CG4+ Kit Lot# D2093 Exp Date 6/19/21, and one patient tested on 9/15/2021 with Chem 8+ Kit Lot# H20356 Exp Date: 6-19-2021. 2. A review of the i-STAT 1 System Manual revealed that the laboratory failed to follow the manufacturer's instructions as stated, "Ensure that cartridges are not used after the expiration date printed on the individual package and box." 3. A review of Standard Operating Procedures revealed the laboratory failed to follow their procedure as stated in "Reagents, Controls, Test Kits and Media: E. Outdated materials will be discarded immediately as directed by the manufacturer." 4. An interview on February 15, 2023, at 11:00 AM with the LD #1 confirmed the laboratory failed to ensure i-STAT Chem 8+ and CG 4+ cartridges were not used past their expiration dates for two or two patients tested on September 15, 2021, and November 14, 2021.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(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--
(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. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation, review of product insert, Individualized Quality Control Plan (IQCP) and interview with the Laboratory Director (LD) #1, the laboratory failed to follow the manufacturer's instructions for the type of urine and serum quality controls dictated by QuickVue+ hCG Combo Test product insert from February 15, 2021 to February 15, 2023. Findings: 1. Observed in the laboratory refrigerator two McKesson bottles of Premium Liquid Urine Control Level 1 and Level 2 available for use as HCG controls. No serum HCG controls were available. 2. A review of QuickVue+ hCG Combo Test package insert for the detection of HCG in urine and serum revealed the laboratory failed to follow manufacturer's instructions as stated, " The hCG Control Set - Serum (Cat. #00281) or the hCG Control Set - Urine (Cat. #00272) can be used for this purpose. The use of other hCG controls may be incompatible with the assay." 3. The IQCP Quality Control Plan hCG Combo Rapid Test lacks information regarding quality controls material for serum and urine controls specified by the manufacturer's insert. 4. An interview with (LD) #1 on February 15, 2023, at 12:35 PM, confirmed the laboratory failed to use the quality control sets dictated by QuickVue+ hCG Combo Test product insert from February 15, 2021 to February 15, 2023.

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 hematology quality control (QC) records, policies and procedures, and an interview with the Laboratory Director (LD) #1, the laboratory failed to follow their procedure and verify the new lots of quality control material performed on the Sysmex XN 300 hematology analyzer from February 15, 2021 to February 15, 2023. Findings: 1. The laboratory failed to follow their Standard Operating Procedures as stated, "Quality Control, E. New lots of quality control will be verified against pervious lot with at least 5 data points." 2. No concurrent studies of lot-to-lot changes of quality control materials for the Sysmex XN 300 were available for review. 3. An

interview with (LD) #1 on February 15, 2023, at 11:45 AM, confirmed the laboratory failed to verify new lots of QC material for the Sysmex XN 300 analyzer from February 15, 2021 to February 15, 2023.

D5537

ROUTINE CHEMISTRY
CFR(s): 493.1267(b)(d)

For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of quality control (QC) records, Individualized Quality Control Plan (IQCP) for i-STAT CG4+ cartridge (blood gas) and interview with the Laboratory Director (LD) #1, the laboratory failed to perform the internal electronic simulator for six out of six patients tested and perform external quality controls at the frequency required by their Individualized Quality Control Plan (IQCP) from June 18, 2021 to February 02, 2023. Findings: 1. A review of the i-STAT Electronic Simulator records for Abbott i-STAT CG4+ cartridge (pH, oxygen partial pressure, carbon dioxide partial pressure and lactate) performed on six patients tested on 4/28/22, 5/18/22, 8/17/22, 1/11/23, 2/1/23 and 2/2/23 lacked corresponding daily electronic simulator checks. 2. A review of iSTAT test cartridge log-in sheet lacked records of new kit lot#, expiration date and three levels of external QC performed for new CG4+ cartridge kits from June 18, 2021 to June 3, 2022. 3. A review of "IQCP Quality Control Plan i-STAT" revealed the laboratory failed to perform or document the internal control simulator as stated, "With each patient tested," and perform external control as stated, "3 levels QC with each new lot # of cartridge." 4. An interview with LD#1 on February 15, 2023, at 11:20 AM, confirmed the laboratory failed to follow and perform external QC and the electronic simulator at the frequency required by their IQCP for the i-STAT CG4+ cartridge from June 18, 2021 to February 02, 2023.