

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 27D2273368	<b>(X3) Date Survey Completed</b> 08/27/2024
<b>Name of Provider or Supplier</b> Billings Clinic West Yellowstone	<b>Street Address, City, State</b> 236 Yellowstone, West Yellowstone, MT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review, product inserts, and interview with a laboratory director (LD) #1, laboratory staff failed to follow the manufacturer's instructions to perform an external positive and negative quality control (QC) monthly as required by Sure Vue Serum/Urine human chorionic gonadotropin (hCG) product insert for 3 out of 3 months from June 14, 2024 to August 27, 2024. Findings: 1. A review of quality control (QC) records for hCG urine testing revealed the laboratory failed to perform an external positive and negative control monthly per the Sure Vue Serum/Urine hCG product insert for months June, July, and August 27, 2024. 2. A review of the "Urine Pregnancy Test-Patient Log" revealed seven urine pregnancy tests were performed on patients from June 14, 2024, to August 27, 2024. 3. An interview with the LD #1 on August 27, 2024, at 2:00 PM confirmed testing personnel failed to perform monthly external positive and negative QC per the Sure Vue Serum/Urine hCG product insert from June 14, 2024, to August 27, 2024.</p>
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units</p>

of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of patient results reports and interview with the laboratory director (LD) # 1, the laboratory failed to list the address of the testing laboratory on eight patient results reports for tests performed on the Abbott iSTAT analyzer from July 1, 2024, to August 27, 2024. Findings: 1. A review of patient results reports for iSTAT cartridges Chem 8 (Sodium (Na), Potassium (K), Chloride (Cl), Carbon Dioxide (TCO<sub>2</sub>), Ionized Calcium (iCa), Glucose (Glu), Urea Nitrogen (BUN), Creatinine (Crea), Hematocrit (Hct), Hemoglobin (Hgb), Anion Gap), cartridges CG4 (Lactate, pH, Partial pressure of carbon dioxide (PCO<sub>2</sub>), Base Excess (BE), Oxygen saturation (sO<sub>2</sub>), Bicarbonate (HCO<sub>3</sub>), and Partial pressure of oxygen (PO<sub>2</sub>)), cartridges cTN1 (cardiac troponin I), and cartridges BNP (B-type Natriuretic Peptide) lacked the testing facility's address listed on the report. 2. Based on the test volume sheet, six patients were tested with the chem-8 cartridge, one patient was tested with the BNP cartridge, and one patient was tested with the CG4 cartridge. Tests were performed using the Abbott iSTAT analyzer. 3. An interview with LD # 1 on June 23, 2022, at 12:35 PM confirmed the laboratory's patient results report failed to list the address of the laboratory location where the test was performed from July 1, 2024, to August 27, 2024.

**D5807**

TEST REPORT

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of patient results reports and interview with the laboratory director (LD) # 1, the laboratory failed to include the normal reference ranges on the patient results reports for 20 out of 20 analytes resulted from the Abbott iSTAT analyzer from July 1, 2024, to August 27, 2024. Findings: 1. A review of the iSTAT patient results reports for Sodium (Na), Potassium (K), Chloride (Cl), Carbon Dioxide (TCO<sub>2</sub>), Ionized Calcium (iCa), Glucose (Glu), Urea Nitrogen (BUN), Creatinine (Crea), Hematocrit (Hct), Hemoglobin (Hgb), Anion Gap, Lactate, pH, Partial pressure of carbon dioxide (PCO<sub>2</sub>), Base Excess (BE), Oxygen saturation (sO<sub>2</sub>), Bicarbonate (HCO<sub>3</sub>), and Partial pressure of oxygen (PO<sub>2</sub>), cardiac troponin I, and B-type Natriuretic Peptide (BNP) lacked normal reference ranges (measured and calculated) listed on the reports. 2. An interview with LD #1 on August 27, 2024, at 11:07 AM confirmed the patient results report lacked normal reference ranges for the analytes resulting from the Abbott iSTAT analyzer from July 1, 2024, to August 27, 2024.

**D5817**

TEST REPORT

CFR(s): 493.1291(i)

If a laboratory refers patient specimens for testing-- (i)(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory; (i)(2) The referring laboratory may permit each

testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and (i)(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed.

This STANDARD is not met as evidenced by:

Based on a review of patient results reports, and interview with the laboratory director (LD) # 1, laboratory staff failed to have an exact duplicate of the reference laboratory's patient results report from February 27, 2023, to August 27, 2024.

Findings: 1. Testing personnel (TP) #1 failed to provide an exact copy of the reference laboratory's (27D0409764) patient results report for a complete metabolic panel performed on 8/27/2024. 2. An interview with LD #1 on August 27, 2024, at 12:45 PM confirmed testing personnel did not have access to be able to provide an exact copy of the reference laboratory's patient results report from February 27, 2023, to August 27, 2024.