

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D0652481	<b>(X3) Date Survey Completed</b>  09/12/2018
<b>Name of Provider or Supplier</b>  Poplar Community Hospital Nemhs	<b>Street Address, City, State</b>  211 H Street, Poplar, 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>D0000</b>	Based on an on-site recertification survey conducted on 9/12/18, deficiencies were cited for Poplar Community Hospital in Poplar, MT.
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> 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 observation, record review, and interview, the laboratory failed to enroll in proficiency testing for rubella and human immunodeficiency virus (HIV) from 1/1/17 through 9/12/18. The findings include: 1. On 9/12/18 at 9:30 a.m., a HIV kit and a rubella kit were observed in the laboratory. 2. A review on 9/12/18 at 10:27 a.m. of the American Proficiency Institute (API) binders lacked documentation of proficiency testing enrollment for HIV and rubella. 3. A review on 9/12/18 at 10:44 a.m. of the API 2018 Order Confirmation list lacked enrollment for HIV and rubella. 4. On 9/12/18 at 10:44 a.m., staff member A stated they forgot to enroll in 2018 for those analytes.</p>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must</p>

attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory director failed to sign 8 of 8 attestation statements in 2018. The findings include: 1. A review on 9/12/18 at 10:30 a. m. of the American Proficiency Institute (API) binders lacked lab director signatures on the attestation statements for events one and two of 2018. a. Immunology /Immunochemistry. b. Chemistry core. c. Miscellaneous chemistry. d. Hematology /coagulation. 2. On 9/12/18 at 10:30 a.m., staff member B stated the attestations were not signed.

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview, the laboratory failed to perform accuracy verification or enroll in proficiency testing for beta-hydroxybutyrate (BHB) from 1/1/17 through 9/12/18. The findings include: 1. On 9/12/18 at 9:30 a.m., a BHB meter was observed in the laboratory. 2. A review on 9/12/18 at 10:27 a.m. of the American Proficiency Institute (API) binders lacked documentation of proficiency testing enrollment or accuracy verification for BHB. 3. A review on 9/12/18 at 10:44 a. m. of the API 2018 Order Confirmation list lacked enrollment for BHB. 4. On 9/12/18 at 10:44 a.m., staff member A stated they forgot to enroll in 2018 for BHB.

**D5411**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(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 observation, record review, and interview, the laboratory failed to follow manufacturer directions for the establishing a mean of the patient normal range with each new lot of RecombiPlasTin 2G reagent from 9/13/16 through 9/12/18. The findings include: 1. On 9/12/18 at 9:30 a.m., a Stago ACL Elite analyzer was observed in the laboratory. 2. On 9/12/18 at 9:30 a.m., staff member A stated prothrombin times (PT) and partial thromboplastin time (PTT) were performed on the Stago ACL Elite. 3. On 9/12/18 at 2:40 p.m., a normal patient mean of 12.0 seconds was observed on the ACL Elite analyzer for the RecombiPlasTin 2G lot number N0579856 which expired on 5/31/19. 4. On 9/12/18 at 2:40 p.m., a review of the current bottle of RecombiPlasTin reagent in use was lot number N0177148 which expired on 1/31/19. 5. A review on 9/12/18 at 2:40 p.m. of the manufacturer instructions for

RecombiPlasTin 2G reagent for the ACL Elite analyzer included instructions to enter "the ISI value from the insert and establish the mean of the PT normal range with each new lot." 6. On 9/12/18 at 2:40 p.m., staff member A stated the mean was not found.

**D5555**

**IMMUNOHEMATOLOGY**  
CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to perform regular alarm checks on the blood bank refrigerator from 1/1/17 through 9/12/18. The findings include: 1. A review on 9/12/18 at 2:50 p.m. of the blood bank binders lacked documentation of alarm checks in 2017 and had only two alarm checks (1/18 and 8/18) in 2018. 2. On 9/12/18 at 2:50 p.m., staff member A stated the policy for alarm checks was the same policy as a collaborating facility which required quarterly testing of the lower level and higher level alarm activation.