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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 27D0409444 | (X3) Date Survey Completed 03/13/2018 |
| Name of Provider or Supplier Beartooth Billings Clinic | Street Address, City, State 2525 North Broadway, Red Lodge, 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 |
|---------------------------|--|
| D0000 | Based on an on-site recertification survey conducted on 3/13/18, deficiencies were cited for Beartooth Billings Clinic in Red Lodge, MT. |
| D2010 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to test proficiency samples the same number of times as patient samples for three of three proficiency events in 2017. The findings include: 1. A review on 3/13/18 at 8:40 a.m. of the American Proficiency Institute (API) blood bank attestation documents included multiple testing personnel signing for testing blood bank samples. 2. A review on 3/13/18 at 3:00 p.m. of the Beartooth Billings Clinic blood bank patient log included multiple API test result entries for each event in 2017, while patients included one test result. a. 2017 event 1 included results for testing on 4/6/17, 4/10/17, and 4/12/17. b. 2017 event 2 included results for testing on 8/9/17 and 8/16/17. c. 2017 event 3 included results for testing on 12/8/17, 12/11/17, and 12/21/17. 3. On 3/13/18 at 3:30 p.m., staff member A stated each testing person performed API testing for each event to maintain competency due to low patient volume. 4. On 3/13/18 at 3:30 p.m., staff member B stated the results submitted to API were from the first person testing the samples most of the time due to degradation of the product over time. 5. A review on 3/13/18 at 4:00 p.m. of the Beartooth Billings Clinic Handling of Proficiency Testing Samples Policy stated "samples MUST be tested in the same manner as patient samples." 6. A review on 3/13/18 at 4:00 p.m. of the API webpage for Beartooth Billings Clinic showed results were submitted to API after multiple testing personnel</p> |

had tested the samples. a. 2017 event 1 results were submitted to API on 4/13/17. b. 2017 event 2 results were submitted to API on 8/17/17. c. 2017 event 3 results were submitted to API on 12/12/17.

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 for potassium hydroxide (KOH) preps at least twice annually from 3/25/16 through 3/13/18. The findings include: 1. A review on 3/13/18 at 8:40 a. m. of the American Proficiency Institute (API) documentation lacked proficiency testing enrollment for KOH. Accuracy verification was not documented. 2. On 3/13 /18 at 8:40 a.m., staff member B stated KOH preps are performed in the laboratory and API was not enrolled for KOH. 3. On 3/13/18 at 8:55 a.m. the Remel KOH reagent vials were observed next to the microscope in the laboratory. 4. A review on 3 /13/18 at 8:50 a.m. of the test volume report for Beartooth Billings Clinic included an annual test volume of 12 KOH preps.

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 on the Sysmex CA-600 analyzer for one of three tests performed on that analyzer from 3/25/16 through 3/13/18. The findings include: 1. On 3/13/18 at 8:15 a.m. a Sysmex CA-600 analyzer was observed in the laboratory. 2. On 3/13/18 at 8:15 a.m., staff member B stated D-dimer, prothrombin time (PT), and partial thromboplastin time (PTT) are performed on the Sysmex CA-600. 3. A review on 3/13/18 at 8:50 a.m. of the annual test volume report for Beartooth Billings Clinic included 2046 PTs performed annually. 4. On 3/13/18 at 12:00 p.m., a normal patient mean of 10.0 seconds was observed on the analyzer for calculation of the international normalized ratio (INR). 5. A review on 3/13/18 at 12:00 p.m. of the calculated patient mean for the current lot of Innovin in use was 10.3 seconds. The calculated patient mean for the previous lots of Innovin were 10.3 seconds and 10.7 seconds. 6. On 3/13 /18 at 12:00 p.m., staff member A stated the mean was different. 7. A review on 3/13 /18 at 12:30 p.m. of the Beartooth Billings Clinic Determination of INR policy stated in the notes section the "normal PT is defined as the mean of the normal range and must be specifically determined for each lot of thromboplastin." Instructions on entering the mean normal PT into the analyzer was not included. 8. A review on 3/13 /18 at 12:30 p.m. of the Beartooth Billings Clinic Prothrombin Time Normal Range

policy stated "determine the mean, standard deviation (SD) and range once the data has been collected." Instructions on entering the mean normal PT into the analyzer was not included.