

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0879413	(X3) Date Survey Completed 05/21/2019
Name of Provider or Supplier Logan Health Primary Care Eureka	Street Address, City, State 304 Osloski Road, Eureka, 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 5/21/19, deficiencies were cited for Eureka Healthcare Primary Care in Eureka, MT.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to perform twice a year accuracy verification for wet mounts and potassium hydroxide (KOH) tests from 9/14/17 to 5/21/19. The findings include: 1. On 5/21/19 at 10:00 a.m. a microscope was observed in a cupboard in the laboratory. 2. A review on 5/21/19 at 10:30 a.m. of the College of American Pathologists (CAP) proficiency testing documentation lacked proficiency testing enrollment for wet mounts and KOH. 3. On 5/21/19 at 10:30 a.m., staff member A stated the laboratory did not have proficiency testing enrollment and had not performed accuracy verification for wet mounts and KOH.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on observation, record review, and interview, the laboratory failed to perform quality control (QC) with the frequency stated in the laboratory procedure from 4/21/18 to 5/8/19. The findings include: 1. On 5/21/19 at 10:00 a.m. a Coaguchek XS Pro analyzer was observed in the laboratory. 2. A review on 5/21/19 at 12:20 p.m. of the Coaguchek Result Summary list of QC results lacked monthly controls performed on the Coaguchek XS Pro between 4/21/18 and 5/8/19. 3. A review on 5/21/19 at 12:45 p.m. of the Coaguchek XS Pro/Plus Protime/INR Patient Testing Policy stated "two levels of liquid controls (low and high) are performed monthly, with each new shipment and/or lot number of strips. Whichever is more frequent." 4. On 5/21/19 at 12:45 p.m., staff member A stated the control data was not uploaded electronically due to a firewall and was deleted off the analyzer during a system upgrade. Printed copies were not available. 5. A review on 5/21/19 at 1:00 p.m. of the monthly reminder list for April 2019 checked the Coaguchek monthly controls as completed on 4/18/19.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to perform competency assessments for one of seventeen testing personnel in 2017, 2018, and 2019. The findings include: 1. A review on 5/21/19 at 11:15 a.m. of the competency assessments lacked competency assessments for staff member B. 2. On 5/21/19 at 11:45 a.m., staff member A stated staff member B had not completed competency assessments.