

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0410720	(X3) Date Survey Completed 03/06/2019
Name of Provider or Supplier Deer Lodge Medical Center	Street Address, City, State 1100 Hollenback Lane, Deer 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 3/6/19, deficiencies were cited for Deer Lodge Medical Center in Deer Lodge, MT.
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 observation, record review, and interview, the laboratory failed to enroll in proficiency testing for two of three molecular panels performed on the Biofire Filmarray from 6/30/17 through 3/6/19. The findings include: 1. On 3/6/19 at 9:15 a.m., a Biofire Filmarray was observed in the laboratory. 2. On 3/6/19 at 9:15 a.m., staff member A stated the respiratory panel, gastrointestinal (GI) panel, and blood panels were performed on the Biofire Filmarray. 3. A review on 3/6/19 at 10:00 a.m. of the American Proficiency Institute (API) and American Association of Bioanalysts (AAB) proficiency testing binders lacked documentation of enrollment for the GI and blood panels performed on the Biofire Filmarray. 4. On 3/6/19 at 10:00 a.m., staff member A stated plate culture enrollment was used for the Biofire Filmarray GI and blood panels. 5. On 3/6/19 at 11:30 a.m., staff member A stated the plate culture enrollment did not report all of the viruses, bacteria, and parasites identified by the GI and blood panels.</p>

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory technical supervisor failed to perform annual competency evaluations on one of four testing personnel in 2017 and 2018. The findings include: 1. A review on 3/6/19 at 11:15 a.m. of the competency assessments lacked documented competency on staff member A. 2. On 3/6/19 at 11:15 a.m., staff member A stated competency assessments were not performed.