Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0663007	06/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Central Montana Medical Center	408 Wendell Ave, Lewistown, 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 6/25/18-6/26/18, deficiencies were cited for Central Montana Medical Center in Lewistown, MT.
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain in-house data for 12 of 12 Individual Quality Control Plans (IQCPs) reviewed. The findings include: 1. A record review on 6/26/18 at 11:15 a.m. of the IQCP binder lacked the in-house data utilized to support the number and frequency of controls for 12 IQCPs. a. Human immunodeficiency virus (HIV), blood culture identification panels, clostridium difficile (C. diff), campylobacter, gastrointestinal identification panels, group b strep, human chorionic gonadotropin (hCG), antimicrobial susceptibility tests, respiratory syncytial virus (RSV), shiga toxin, and urine drug screens. 2. On 6/26/18 at 11:30 a.m., staff member A stated the data was not retained in the binder and some data was not retrievable anymore.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by:

	Based on record review and interview, the laboratory director failed to sign and date approval of 12 of 12 Individual Quality Control Plans (IQCPs). The findings include: 1. A review on 6/25/18 at 2:25 p.m. of the IQCP binder lacked signatures of approval by the current laboratory director on 12 IQCPs. a. Human immunodeficiency virus (HIV), blood culture identification panels, clostridium difficile (C. diff), campylobacter, gastrointestinal identification panels, group b strep, human chorionic gonadotropin (hCG), antimicrobial susceptibility tests, respiratory syncytial virus (RSV), shiga toxin, and urine drug screens. 2. On 6/25/18 at 2:25 p.m., staff member A stated the IQCPs were not signed by the laboratory director.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to document the temperature of the cryostat when in use from 8/3/16 to 6/25/18. The findings include: 1. On 6/25 /18 at 11:30 a.m., a cryostat was observed in the laboratory. 2. On 6/26/18 at 11:00 a. m., staff member A stated the temperature of the cryostat when in use was not documented.
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 evaluate and document competency on one of 8 testing personnel in 2017 and 2018. The findings include: 1. A review on 6/25/18 at 1:30 p.m. of the competency evaluations lacked evaluations for staff member A in 2017 and 2018. 2. On 6/25/18 at 1:30 p.m., staff member A stated competency evaluations were not completed for staff member A.