

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D1028781	(X3) Date Survey Completed 04/11/2018
Name of Provider or Supplier Adlera Laboratory, Llc	Street Address, City, State 601 1st Avenue North, Great Falls, 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 4/11/18, deficiencies were cited for Central Montana Laboratory in Great Falls, MT.
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to state the number of controls used in one of two Individual Quality Control Plans (IQCPs) reviewed. The findings include: 1. A review on 4/11/18 at 4:03 p.m. of the Central Montana Laboratory Stratus Quality Control Plan Worksheet lacked the number of controls to be performed for b-type natriuretic peptide (BNP). 2. On 4/11/18 at 4:03 p.m., staff member A stated two controls are performed.</p>