Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 27D1028781	**(X3) Date Survey Completed** 03/21/2019
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 off-site proficiency testing desk review conducted on 3/21/19, deficiencies were cited for Adlera Laboratory, LLC in Great Falls, MT.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on routine desk audit of CMS-153 and 155 reports of proficiency testing performance and interview, the laboratory failed to achieve satisfactory performance for blood urea nitrogen (BUN) for two consecutive (2018 event 3 and 2019 event 1), resulting in unsuccessful proficiency testing performance. See D2096.
D2096	ROUTINE CHEMISTRY

	CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of proficiency testing scores and interview, the laboratory failed to achieve a score of 80 percent for blood urea nitrogen (BUN) in two consecutive events in 2018 and 2019, resulting in unsuccessful performance. The findings include: 1. During a review on 3/18/19 at 11:30 a.m. of the CMS-153 Unsuccessful Proficiency Testing Report included Adlera Laboratory, LLC with unsuccessful proficiency testing scores for BUN. 2. During a review on 3/20/19 at 8:00 a.m. of the CMS-155 report, the American Proficiency Institute (API) BUN score for event 3 of 2018 was 0%. 3. During a review on 3/20/18 at 8:00 a.m. of the CMS-155 report, the API BUN score for event 1 of 2019 was 60%. 4. On 3/21/19 at 9:30 a.m., the laboratory manager stated the failures occurred and corrective action is in process.