Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1093224	07/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Altheadx Inc	3737 N 7th St, Ste 160, Phoenix, AZ	

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
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(g) 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-- Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, patients sample and quality control testing records, and interview with the laboratory Director and testing personnel, the laboratory failed to test control materials in the same manner as patient specimens. The findings include: a. The laboratory does not test the required 2 levels of control materials in the same manner as patient specimens. The laboratory uses 2 levels of quality control materials, low and high levels, at the DNA extraction step which is the 1st step in the analytical phase of testing. Only one of the control, the high level one, goes through all the subsequent steps in the analytical phase of testing. The laboratory does not test the other control, the low level one, further in the subsequent steps in the analytical phase of testing. However, after the DNA extraction step (the 1st step in the analytical phase of testing) is completed, the laboratory introduces a new control, negative control, that goes through to the subsequent steps in the analytical phase of testing. b. On July 18, 2018 at 2:30 pm laboratory director affirmed that only one level of control materials is tested in the same manner as patient specimens throughout all the steps in the analytical phase of testing. c. The laboratory's testing declaration form, signed by the laboratory Director on July 05, 2018, stated that the laboratory performs 411,341 tests annually.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)

	The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on Surveyor review of quality control testing records, and interview with the laboratory Director and testing personnel, the laboratory Director failed to ensure that the testing system developed and used provide quality laboratory services for all aspects of analytical phase of testing . The findings include: a. See D5465