Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2011324	03/30/2021
Name of Provider or Supplier	**Street Address, City, State**	
New Horizons Medical Pc	186 Cedar Hill Street, Marlborough, MA	

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	A CLIA recertification survey was conducted for the New Horizons Medical, PC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on interview and procedural review, the laboratory failed to have a written procedure describing the system that twice a year evaluates and defines the relationship between test results using two Liquid chromatography/mass spectrometry (LC/MS) analyzers as evidenced by the following: a) The laboratory performs twice annual comparisons for drug of abuse analytes on the two LC/MS analyzers. A procedure describing the steps for performing and evaluating the comparison could not be found during a review of the laboratory's procedure manual. b) The technical supervisor confirmed in an interview on 3/30/21 at 12:34 PM that a written procedure for twice annual comparisons of the two LC/MS analyzers was not available.