Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0383600	04/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Unitypoint Clinic Family Medicine	2103 Ingersoll Avenue, Des Moines, IA	

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
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 review of the Clinical Laboratory Improvement Amendments (CLIA) Application (Form CMS-116), laboratory humidity and temperature records, Sysmex XP-300 maintenance records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) and the clinic manager at approximately 4: 00 pm on 04/19/2018, the laboratory failed to monitor and document humidity, room temperature, and the laboratory refrigerator and freezer temperatures for five out of 226 days of patient testing (10/29/2017, 11/19/2017, 11/25/2017, 11/26/2017, and 12 /03/2017) from 08/01/2017 to 03/31/2018. The findings include: 1. According to the CLIA Application, Form CMS-116 received in May 2016, the laboratory held hours of operation Monday through Saturday of each week. In September 2017, laboratory personnel identifier #2 notified the Iowa State Agency office that the laboratory would begin holding hours of operation Sunday through Saturday of each week on October 23, 2017. 2. Review of the laboratory's humidity and temperature records and the Sysmex XP-300 complete blood count (CBC) analyzer maintenance records revealed that the laboratory performed maintenance on the Sysmex analyzer but did not document humidity, room temperature, refrigerator, or freezer temperatures on the following dates: 10/29/2017, 11/19/2017, 11/25/2017, 11/26/2017, and 12/03/2017. 3. Laboratory personnel identifier #2 and the clinic manager confirmed that the

	laboratory held hours of operation on the previously mentioned dates, but did not document humidity, room temperature, refrigerator, or freezer temperatures.