Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2006336	12/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cyrex Laboratories, Llc	2602 S 24th St, 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
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 manufacturer's instrument specifications for the Beckman Coulter Immage 800, review of the laboratory's established ambient relative humidity range and interview with the laboratory personnel, the laboratory's humidity range did not meet the acceptable humidity range indicated by the manufacturer. Findings include: 1. The laboratory's current humidity range indicated on the log sheet is 2% -74%, while the manufacturer's humidity range indicated in the operations manual is 15%-85%. 2. The laboratory personnel acknowledged that the ranges were not compatible. 3. The humidity recordings indicated on the log did not fall below 15% or above 85% since the instrument was utilized for patient testing starting in September 2018.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) documentation, quality control records and interview with the facility personnel, the laboratory failed to identify errors found in the analytic systems. Findings include: 1. The laboratory began patient testing on the Beckman Coulter Immage 800 test system in September 2018 under the sub-specialty of General Immunology. The laboratory performs a Total Serum IgG/IgA/ IgM (GAM) test on this analyzer. 2. It is the practice of the laboratory to perform 3 levels of Quality Control (QC) for the GAM test, Low, Normal and High. The QC lot information for each level is manually entered into the instrument, including control ranges and lot number. The laboratory manually documents daily QC results and QC information on an "Assay Coversheet", which is reviewed for acceptance and accuracy by several laboratory personnel. 3. The Assay Coversheet for GAM testing performed on 11/16/18 indicated the Low QC Lot# as M710251 and the Normal QC Lot# as M710252. The QC information entered in the analyzer from 11/16/18 indicated the Low QC Lot# as M805011 and the Normal QC Lot# as M805012. 4. No corrective action documentation was presented for review to indicate the laboratory identified the error of maintaining the incorrect lot numbers on the analyzer for the Low and Normal levels of QC for patient testing that occurred on 11/16/2018. 5. During the survey the laboratory personnel confirmed that the lot information entered on the Assay Coversheet was correct and the laboratory failed to update the lot numbers in the analyzer. 6. The facility personnel confirmed that the laboratory's daily review of quality control results and information for the GAM test failed to identify errors found in the analytic systems.