Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2079383	01/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Firmus Labs	9001 Woodyard Road #A-2, Clinton, MD	

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 remote review of facility logs and phone interview conducted on 01/28/2021 with the technical supervisor (TS), the laboratory failed to document corrective actions when temperature and humidity values were outside of defined acceptable ranges. Findings: 1. The laboratory's ambient temperature and humidity logs from July 2018-December 2020 were reviewed. The acceptable range for temperature was defined as 18-25C (degrees Celsius) and for humidity 40-80%. 2. The temperature was recorded as 27C for 2 days in February 2019 and 5 days in March 2019 with no record of corrective actions or monitoring. 3. The humidity was recorded as 26%, 31%, 32% and 33% for one day each and 37% for two days in October 2018 and 26% for one day in November 2018 with no record of corrective actions or monitoring. 4. The laboratory's freezer logs from July 2018-December 2020 were reviewed. There were two ranges defined on the log; "Temperature: -20.0C 5C" and "Specification: -15.0C to -30.0C". The TS stated that the "Specification" is the acceptable temperature range. 5. The documentation for freezer 2 showed that the temperature was recorded as -33.7C and -33.8C for one day each in January 2019 with no record of corrective actions or monitoring. 6. One day after the phone interview, the TS sent an "Action Log" for the ambient temperatures and a separate "Action Log" for the freezer temperatures that were out of range, both signed on 01/29/2021,

	retrospectively documenting the corrective actions that were taken. 7. The laboratory failed to document the corrective actions for unacceptable temperatures at the time of the events.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on remote survey record review and phone interview on 01/28/2021 with the technical supervisor (TS), the laboratory failed to ensure that the manufacturer's preventive maintenance was performed as defined in the ImmTox maintenance manual. Findings: 1. The ImmTox analyzer monthly maintenance worksheets for the months of July 2018 through November 2020 were reviewed remotely. 2. The daily maintenance was documented but no monthly maintenance was documented as required during the months of January, April, and December 2019 and January, February, and April 2020. 3. The daily maintenance was documented but no weekly maintenance was documented as required during the months of December 2019, January 2020 and February 2020. 4. The daily maintenance was documented but no weekly maintenance was documented as required for 1 of 4 weeks during the months of June, July, and August 2019, and April 2020. 5. The daily maintenance was documented but no weekly maintenance was documented as required for 3 of 4 weeks in September, October, and November 2019. 6. The daily maintenance was documented once a week for 3 days in September 2020 and the weekly maintenance was documented only 1 of the 3 weeks. 7. The daily shutdown was not performed as required during the months of April 2019 for 2 of 10 days that maintenance was recorded, January 2020 for 9 of 14 days that maintenance was recorded, and February 2020 for 14 of 20 days that maintenance was recorded. 8. The laboratory did not perform daily, weekly, and monthly maintenance per the manufacturer's instructions. 9. During the phone interview on 01/28/2021 the TS stated that the manufacture of the ImmTox stated that the maintenance could be performed less frequently based on test volume. The documentation that was emailed on 01/29/2021 did not confirm this statement.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on remote survey record review and phone interview on 01/28/2021 with the technical supervisor (TS), the laboratory director (LD) failed to ensure that the comparison studies performed between the two liquid chromatography with tandem mass spectrometry (LC-MS/MS) analyzers were evaluated and approved at the time the comparisons were performed. Findings: 1. On 12/15/2020, the laboratory submitted comparison studies performed between the two LC-MS/MS analyzers for

	2018 and 2020. The records did not include a date of approval and an evaluation of acceptability of the comparison by the LD. 2. During the phone interview on 01/28 /2021 at 10:30 AM, the TS stated that the laboratory had performed the comparison evaluation and that it was at the end of the document. The comparison documentation that was submitted on 12/15/2020 was resubmitted on 01/29/2021 with an evaluation of the comparison between the two analyzers added at the end of the document on the second page. 3. The documentation that was originally submitted did not show that the data had been initially evaluated and approved at the time the testing was performed in 2018 and 2020.