Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2269232	12/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Biogenics Medical Laboratories	8435 Progress Dr, Suite Dd, Frederick, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the quality control (QC) records and interview with the laboratory consultant (LC), the laboratory failed to ensure that the QC results from each lot has been printed, reviewed, and saved prior to the new lot of QC material being entered into the ImmTox 270 toxicology analyzer. Findings: 1. The laboratory started using the ImmTox 270 at the end of May 2024. The QC records were reviewed. The QC records that were available showed results from September 20, 2024 through December 18, 2024. According the the LC, the analyzer holds QC results until the new lot is entered, then the previous QC data is over ridden with the new lot of QC materials. 2. During the exit interview on 12/18/2024 at 12:30 PM, the LC confirmed that the QC records on the ImmTox 270 had not been maintained for the required two years.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other

	materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the laboratory consultant (LC), the laboratory's procedure manual failed to ensure that the written policies and procedures included instructions for submitting the quality control (QC) results from the ImmTox 270 toxicology analyzer on a monthly basis to the laboratory director (LD) for review. Findings: 1. The laboratory started using the ImmTox 270 at the end of May 2024. The analyzer holds quality control (QC) results until a new lot is entered into the analyzer. Once there is a change in the lot number the previous results are over ridden with the new lot numbers values. 2. While performing a pre survey review, the LC noticed that the QC results had not been printed and sent to the laboratory director (LD) for review along with all the other monthly records and periodic reviews. 3. During the exit interview on 12/18/2024 at 12:30 PM, the LC confirmed that the policy and procedure manual did not contain written instructions for printing the ImmTox 270 QC results and scanning them to the LD for review on a monthly basis.