Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2269232	08/16/2023
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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the specimen handling guide and interview with the testing person (TP) and quality manager (QM), the laboratory's specimen handling guide did not include accurate specimen storage and shipping conditions. Findings: 1. The laboratory received urine toxicology specimens from two outside facilities. 2. The document titled "Toxicology Specimen and Handling Guide" (guide) included instructions for outside facilities to collect, store, and transport patient specimens. 3. The guide stated that "Samples may be stored for up to 7 days refrigerated at 2-8 C after date of collection" and "Samples may be stored at -20C for up to 30 days after collection." At the time of the survey the laboratory had stability data showing that samples were stable when stored at -20C for up to 14 days, not 30 days. 4. The TP stated that all specimens were received on ice packs and typically shipped via United Parcel Service (UPS). The guide stated "A courier will transport specimens" and did not mention that samples must be shipped on ice or refrigerated conditions and could be shipped via UPS. 5. During the survey on 08/16/2023 at 3:00 PM, the TP and QM confirmed that the specimen handling guide did not include accurate specimen storage and shipping conditions.
D6148	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(a)(4)

	The general supervisor is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained. This STANDARD is not met as evidenced by: Based on review of the laboratory records, and interview with the testing person (TP) and quality manager (QM), the general supervisor (GS) failed to monitor the test analysis to ensure that acceptable levels of analytic performance was being maintained. Findings: 1. The laboratory records show that the new TP started performing testing on the liquid chromatography mass spectrometer (LC-MS/MS) analyzer in April 2023. 2. Since the new TP does not have the required one year of experience performing testing on the LC-MS/MS analyzer they are not qualified as the GS. 3. The "Laboratory Personnel Report (CLIA)" form lists the name of the GS. The laboratory records show the initial training of the GS on 05/30/2023. There were no records available at the time of the survey showing that the GS was routinely monitoring the test analyses of the new TP. 4. During the exit interview on 08/16 /2023 at 3:00 PM, the TP and QM confirmed that there were no records available at the time of the survey showing that the GS was routinely monitoring the test analyses of the new TP to ensure acceptable levels of analytic performance was being maintained.