

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0411786	(X3) Date Survey Completed 05/16/2023
Name of Provider or Supplier Biotrition Inc	Street Address, City, State 3633 West Lake Ave, Ste 201a, Glenview, IL	
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
D3039	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5)</p> <p>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to maintain laboratory quality system assessment records for monitoring room and equipment temperatures for hematology testing in 2021. Findings Include: 1. Review of laboratory records and lack of documentation revealed the laboratory failed to maintain the documented temperature records for one of one testing year (2021, affecting 93 tests performed) for the following: a. Daily ambient room temperatures b. Daily refrigerator temperatures c. Daily freezer temperatures 2. On 05/16/2023 at 11:20 a.m., the LD stated, "The temperature log book for 2021 was discarded in preparation for retirement in December 2023."</p>