Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 23D0709666	**(X3) Date Survey Completed** 07/10/2023
Name of Provider or Supplier Biotech Clinical Laboratories, Inc	**Street Address, City, State** 25775 Meadowbrook Road, Novi, MI	
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**
D0000	The purpose of this unannounced survey was for complaint #MI00137786. The Department of Licensing and Regulatory Affairs has evaluated this facility and determined that it is not in compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003).
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: . Based on record review and interview with the Quality Assurance Manager, the laboratory failed to ensure it documented all complaints reported to the laboratory for 1 (Patient 30176) of 2 patient complaints reviewed. Findings include: 1. A review of the laboratory's "Quality Management Program" revealed a section titled "Occurrence Management" stating, "An Incident report will be used to document a process or procedure that did not have expected outcome, therefore affecting the laboratory's ability to meet its customers' expectations. For example: a. When other services did not follow established policy b. Occasions of patients or employee complaints c. Communication failures within the laboratory and to outside customers d. Problems with technical operations e. Safety f. Quality of patient testing Completed Incident Reports will be submitted to the Quality Coordinator for review and classification. Reports will be filed by classification and studied for useful information and/or trends. Corrective action taken will be documented by responsible person(s). Improvement will be measured by monitoring any reoccurrences, personal observations, interviews and Quality Assurance Committee meetings." 2. An interview on 7/10/23 at 10:45 am with the Quality Assurance Manager revealed the laboratory had received a subpoena for information regarding the testing for Patient 30176 and provided the requested

	documentation. After the subpoena, Patient 30176 had called to complain about the accuracy of test results received and they directed the patient to speak with their provider ordering the testing. 3. The surveyor requested documentation of the complaint made by Patient 30176 on 7/10/23 at 10:45 am and it was not available. 4. An interview on 7/10/23 at 11:34 am with the Quality Assurance Manager confirmed the laboratory had not documented the complaint received from Patient 30176.