

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0965332	(X3) Date Survey Completed 08/18/2021
Name of Provider or Supplier Bio-Tech Clinical Laboratories Inc	Street Address, City, State 9000 Nw 15th St Unit 1, Doral, FL	
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	An unannounced complaint survey, #2021009416, was conducted on 08/17/2021 to 08/18/2021 at BIO-TECH CLINICAL LABORATORIES INC. The laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to provide collection cups to a patient for the home sample collection in July 2021. Findings include: -Record review of clinical lab phlebotomy log, used to register house calls for July 2021 revealed that there was 1 patient that required urine and stool sample on 07/07/2021. - Review of July collection driver log to collect urine and stool samples pending from phlebotomist trip, revealed that on the day of reference no driver went to collect specimens for the patient of reference. - During a telephone interview on 8/18/2021 at 5:00 PM, with the phlebotomist assigned to that patient, confirmed that the patient collected the samples on disposables cups not assigned by the laboratory and she accepted the samples from the patient and later she transferred to the laboratories cup. She confirmed that she failed to notify to the laboratory of this incident.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p>

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 record review and interview, the procedure manual failed to have a procedure for phlebotomy house calls at the time of the complaint from 08/17/2021 to 08/18/2021. Findings include: Review of phlebotomy procedure policy signed by the laboratory director on 04/21/2021 revealed that this procedure failed to include the procedure for phlebotomy and specimen collection instructions for house calls. During an interview on 08/17/2021 at 3:00 PM, the owner acknowledged that the procedure manual failed to include a procedure for house call phlebotomy services at the time of the inspection.