Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0965332	11/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Bio-Tech Clinical Laboratories Inc	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	A recertification survey conducted, 11/6-7/2019 found that Bio-Tech Clinical Laboratories Inc was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of CMS 209 Laboratory Personnel form, review of American Proficiency Institute (API), College of American Pathologists (CAP) and American Association of Bioanalysts (AAB) proficiency testing (PT) records and with interview with Technical Supervisor (TS), the laboratory failed to have all testing personnel (TP) rotate through the testing of PT for the Chemistry, Diagnostic Immunology and Hematology specialties for 2 out of 2 years (2018 and 2019) reviewed. Findings include: 1-Review of CMS 209 form signed and dated by the Laboratory Director (LD) on 10/22/2019 had 5 testing personnel listed (TPA, TP B, TP C, TP D and TP E). 2- Review of API, CAP and AAB PT records for 2018 and 2019, revealed that for TP E, there was no documentation of PT testing in 2018 and 2019 for the specialties of Chemistry, Diagnostic Immunology and Hematology specialties. During an interview on 11/06/2019 at 2:00 PM, TS confirmed that TP E failed to participate in PT during the years of reference.
D2110	TOXICOLOGY CFR(s): 493.845(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory

	performance. This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing (PT) records and staff interview, the laboratory failed 1 out of 3 events for Toxicology during 2018. Findings include: Review of API proficiency records revealed that the laboratory had a score of 60 % for Digoxin and 20 % for Phenytoin resulting in an overall score of 70 % for 3rd event of Toxicology sub-specialty in 2018. During an interview on 11/06/2019 at 2:30 PM, the Technical Supervisor confirmed that the laboratory failed the sub-specialty of reference in PT for the event of reference.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform initial competency assessment for 1 (TP B) out of 5 testing personnel (TP) (TP A, B, C, D and E) and 1 out of 1 Technical Supervisor (TS), failed to perform semiannual competency assessment for 1 (TP D) out of 5 TP (A, B, C, D and E) in 1 out of 2 years reviewed (2018 -2019) and failed to perform annual assessment competency for 1 (TP E) out of 5 TP (A, B, C, D and E) for 2 out of 2 years reviewed (2018 and 2019) Findings include: Review of personnel files revealed that: -There was no documentation of initial competency assessment for TP B and TS in 2019. -There was no documentation of semiannual annual competency assessment for TP D in 2019 - There was no documentation of the annual competency assessment for TP E for 2018 and 2019 During an interview on 11/06/2019 at 2:30 PM, with TS, she confirmed that there was no documentation of the competency assessment for the staff listed above for the period of reference.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to ensure Methylen Blue stain used for reticulocyte count, 10 % Formalin Fixative reagent and C Reactive Protein Test kit (CRP) were removed from the laboratory after the expiration date. Findings include: Observation of the laboratory on 11/6/2019 at 10:00 am, revealed the following expired reagents: -In the storage area a 1-gallon bottle of 10 % Formalin Fixative solution with lot number 82878 expired 5/16/2010. - 1 bottle of Methylene Blue lot 2709C65 expired on 9/2019 next to the Microscope. -In the reagent's

	refrigerator 1 CRP Latex Test Kit with lot 2321 expired 11/1/2019. During an interview on 11/6/2019 at 10:30 am with TP A, she confirmed the existence of the expired reagents listed above.