

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0965332	(X3) Date Survey Completed 07/03/2018
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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on API record review and interview with laboratory owner, the laboratory failed the analyte testing for Creatine Kinase (CK), Total Protein (TP) for the 3rd event of 2017 for the chemistry specialty. Findings include: Review of API record for 2017, showed that the laboratory failed the tests for CK, TP with a 0 % score in the 3rd event of 2017. During and interview on 7/2/2018 at 2:30 pm, the laboratory owner confirmed the laboratory failed the analytes of reference for the 3rd event of 2017</p>
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on API record review and interview with laboratory owner, the laboratory failed the analyte testing for activated partial thromboplastin time (PTT) for the 3rd event of 2017 for the hematology specialty. Findings include: Review of API record for 2017, showed that the laboratory failed the tests for PTT with a 0 % score for the 3rd event of 2017. During and interview on 7/2/2018 at 2:30 pm, the laboratory owner confirmed the laboratory failed the analyte of reference for the 3rd event of 2017</p>
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of patient reports, work lists, equipment printed outs, daily maintenance equipment log, quality assurance (QA) records for September 2017 and interview with laboratory owner (LO) revealed that the laboratory failed to detect and error on LIS system during September 2017. Findings include: Review of final gonorrhea patient reports for 28 patients of September 15, 2017, showed that 16 out of 28 reported as tested on September 15 2017. Maintenance Log of DTS Aptima equipment showed no testing performed on September 15th 2017. Review of Aptima equipment work lists and Aptima printed out for gonorrhea test from September 15th - 20th, 2017 showed that real date test of the patients of reference was on September 20th, 2017. During an interview on 7/3/2018 at 2:30 PM, with the LO, she confirmed the failure to detect the reporting issue on September 2017 quality assessment.

D6088

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)

The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records and interview with staff, the laboratory director failed to ensure on time enrollment of the laboratory for the 2018 Proficiency testing calendar. Findings include: Review of American Proficiency Institute (API) and American Association of Bioanalysts (AAB) records for 2017 and 2018 revealed that there was a late payment to enroll in PT 2018 calendar. During an interview on 7/2/2018 at 2:00 pm. Laboratory owner confirmed that the laboratory failed to enroll on time for the 2018 PT calendar.