

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2104531	(X3) Date Survey Completed 11/01/2019
Name of Provider or Supplier Boca Biolistics Llc	Street Address, City, State 5001 Nw 13th Ave, Pompano Beach, 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 initial certification survey conducted at Boca Biolistics LIC clinical laboratory on 11/01/2019 found the laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on review of CMS 209 Laboratory Personnel form, review of College of American Pathologists (CAP) proficiency testing (PT) records and interview with General Supervisor (GS), the laboratory failed to have all testing personnel (TP) rotate through the testing of PT for the Bacteriology and Diagnostic Immunology specialties for 1 out of 1 year (2019) reviewed. Findings include: 1-Review of CMS 209 form signed and dated by the Laboratory Director (LD) on 10/30/2019 had 2 testing personnel listed (TP A and TP B). 2-Review of employee folders revealed the following initial evaluation dates TP A on 9/28/2018 TP B on 9/28/2018 3-Review of CAP PT records for 2019, revealed the following: - for TP A, there was no documentation of PT testing in Bacteriology and Immunology Specialties for 2019. During an interview on 11/01/2019 at 12:00 PM, GS confirmed that TP A missed to participate in PT during the year of reference in the specialties listed above.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the laboratory did not have a written policy in place for assessing employee competency and failed to perform the 6 months competency assessment for 2 out of 2 testing personnel (TP) (TP A and TP B). Findings include: -Review of procedure manual on 11/1/2019, revealed that there was no written policy for competency assessment of employee competency. - Review of personnel files revealed that there was no documentation of the semiannual competency assessment for TP A and TP B During an interview on 11/01/2019 at 12:00 PM, with GS, he confirmed that there was no documentation of the competency assessment for the TP listed above for the period of reference.