Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2065162	02/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Bioanalysis Diagnostic Laboratories	18173 S Pioneer Blvd Ste K, Artesia, CA	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on reviews and the lack of documentation of the laboratory's 207, 2018, and 2019 verification of accuracy twice a year records, random patient sampling test results, and interview with the Owner, the laboratory failed to perform verification of accuracy twice a year for IL-1Beta Saliva. The finding included: a. Based on reviews and the lack of documentation for verification of accuracy two times per year, random patient sampling test results reviewed covering period from 10/5/2017 to 9/3/2018, the laboratory analyzed and reported IL-1Beta analytes even though there were no verification of accuracy performed. b. The Owner confirmed (2/21/2019, 1400) that the laboratory failed to perform verification of accuracy two times per year.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on reviews of the laboratory's result printouts, and interview with the Owner, the laboratory failed to eatblish corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results

	and reports. The findings included: a. Review of the laboratory's result printout dated 12/07/18, 12:10:23 PM for a proficiency testing sample handwritten appeared to be PT3, for DHEA analyte indicated a result as, "*.***." no other action from the performing testing personnel. b. Review of the computer printout under comments stated," *.***." in RSLT field indicated an invalid concentration." c. For five (5) out of five (5) random patient test results reviewed covering period 10/3/2017 to 1/11 /2019, the laboratory analyzed and reported Endocrinology tests during the period when the proficiency testing was not performed. d. The Owner confirmed (2/21/2019, 1400) that the laboratory failed to perform any corrective action for the nonresult for a test.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on reviews of the laboratory's result printouts, and interview with the Owner, the laboratory failed to document all corrective actions taken when equipment or methodologies that perform outside of established operating parameters or performance specifications; and when Patient test values that are outside of the laboratory's reportable range of test results for the test system. The findings included: a. Review of the laboratory result printouts dated 12/07/18, 12:10:23 PM for a proficiency testing sample handwritten appeared to be PT3, for DHEA analyte indicated a result as, "*.***." no other action from the performing testing personnel. b. Review of the computer printout under comments stated," *.***." in RSLT field indicated an invalid concentration." c. For five (5) out of five (5) random patient test results reviewed covering period 10/3/2017 to 1/11/2019, the laboratory analyzed and reported Endocrinology test during the period when the proficiency testing was not performed. d. The Owner confirmed (2/21/2019, 1400) that the laboratory failed to perform dilution or other method to obtain a DHEA results.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	Based on reviews and the lack of documentation for the verification of accuracy two times per year for the IL-1Beta analyte, interview with the Owner, it was determined that the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. See D 5779 and D5781.