Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1094914	02/24/2020
Name of Provider or Supplier	**Street Address, City, State**	
Lotus Laboratories	10842 Noel St Ste 110, Los Alamitos, 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
D2021	BACTERIOLOGY CFR(s): 493.823(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of proficiency testing reports from CMS (report 155D, Individual Laboratory Profile), review of twelve (12) random patient reports from 01/09/2018 through 12/19/2019, and AAB (American Association of Bioanalysts) proficiency test event summaries for Bacteriology testing for 2019, and an interview with the laboratory technical consultant, the laboratory failed to participate in testing event Q2-2019 constituting an unsatisfactory performance and resulting in the score of 0%. The findings include: a. CMS and AAB proficiency reported an unsatisfactory score of 0% overall for testing in Bacteriology for Q2-2019 for chlamydia trachomatis and Neisseria gonorrhoeae performed on the BDProbeTec instrument system. b. The technical consultant affirmed on 02/24/20 at 14:00 that the laboratory was enrolled in AAB proficiency testing for Bacteriology in 2019, participated in the first event (Q1) and third event (Q3) 2019, but failed to participate in the second event (Q2) 2019, and that no patient testing was done during the period between the Q2 and Q3, 2019. At the time of the CLIA survey no patient testing documents could be retrieved for the period cited.

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of reagent manufacturer product insert, review of quality control docuemts, and interview with the laboratory's technical consultant and patient final reports [medical records (MR)] for the years 2018, 2019 and 2020, it was determined that the laboratory failed to follow manufacturer's instructions and disclose on patients reports limitations on test interpretation for Prostate Specific Antigen, Total (tPSA) tests. The findings included: a. The laboratory performs Prostate Specific Antigen Total (tPSA) testing on the Beckman Access System. The manufacturer's product insert for tPAS testing instructions under "H. Warnings and Precautions 2" states: "The concentration of tPSA in a given specimen determined with assays from different manufacturers can vary due to to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the tPSA assay used." The laboratory's patient test report finding must therefore always contain a statement on the tPSA, assay method used. b. On 02/24 /2020 14:00 the date of the survey, the technical consultant affirmed that the patients' medical records (charts) did not report the testing methodology for tPSA test results as mandated in the manufacturers package insert instructions. c. Based on the laboratory's testing declaration submitted on 02/24/2020 estimated the annual volume of 342 tPSA tests resulted and reported.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the proficiency testing result reports on 02/24/2019 (survey date), and interview with the laboratory technical consultant, it was determined that the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. The findings included: See D2021.