

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0666419	(X3) Date Survey Completed 03/01/2019
Name of Provider or Supplier American Bio-Clinical Laboratories	Street Address, City, State 2730 N Main St, Los Angeles, 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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of random patient testing records, quality control data, and interview with the laboratory technical supervisor, the laboratory failed to include a negative and a positive control material in each day patient specimens are assayed or follow an established IQCP. The findings include: a. The laboratory tested and reported Quantiferon-TB Plus result for the patients, ID # 2098792 and 2098783 as negative and positive, respectively, however no quality control material was included at the day of patient testing. Since no proper quality control materials were used at the day of the patient sample testing, the validity of the obtained and reported result can not be assured. b. The laboratory technical supervisor, on 3/1/2019 at 3:45 pm, confirmed that no quality control material is used for the above tests. c. The laboratory testing declaration form signed by the laboratory director on 2/26/2019 states that the laboratory performs 1,599 tests in mycobacteriology, annually.</p>
D5621	<p>CYTOLOGY CFR(s): 493.1274(c)(1)</p> <p>(c) Control procedures. The laboratory must establish and follow written policies and</p>

procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (1) A review of slides from at least 10 percent of the gynecologic cases interpreted by individuals qualified under 493.1469 or 493.1483, to be negative for epithelial cell abnormalities and other malignant neoplasms (as defined in paragraph (e)(1) of this section). (c)(1)(i) The review must be performed by an individual who meets one of the following qualifications: (c)(1)(i)(A) A technical supervisor qualified under 493.1449(b) or (k). (c)(1)(i)(B) A cytology general supervisor qualified under 493.1469. (c)(1)(i)(C) A cytotechnologist qualified under 493.1483 who has the experience specified in 493.1469(b)(2). (c)(1)(ii) Cases must be randomly selected from the total caseload and include negatives and those from patients or groups of patients that are identified as having a higher than average probability of developing cervical cancer based on available patient information. (c)(1)(iii) The review of those cases selected must be completed before reporting patient results.

This STANDARD is not met as evidenced by:
 Based on Surveyor review of laboratory policy & procedure, random patient testing records, quality control data, and interview with the laboratory coordinator, the laboratory failed to complete the review of the selected gynecological control cases before reporting patient results. The findings include: a. The laboratory's cytotechnologist screened some patient gynecological slides including sample ID: 1527495 on 08/07/2017. The laboratory picked 10% of the screened cases including sample ID: 1528561 for quality control purposes. The record shows that the picked quality control slides were reviewed by the technical supervisor on 08/09/2017. Nonetheless, prior to the completion of control review the laboratory reported the negative result for sample ID: 1527495 on 08/07/2017. Therefore, the validity of the reported result could not be assured. b. The laboratory coordinator, on 3/1/2019 at 3:35 pm, confirmed that the patient results were reported prior to the completion of the review of the control. c. The laboratory testing declaration form signed by the laboratory director on 2/26/2019 states that the laboratory performs 15,965 tests, annually.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
 Based on Surveyor review of patient test records, and policy, procedure and quality control records for cytology and mycobacteriology, and interview with the laboratory technical supervisor and coordinator, it was determined that the laboratory director failed to ensure the quality controls are established to assure the quality of laboratory services provided (See D5445 and 5621).