

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0580198	(X3) Date Survey Completed 04/30/2020
Name of Provider or Supplier Advanced Biomedical, Inc	Street Address, City, State 3098 S Harbor Blvd, Santa Ana, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on desk review of CMS proficiency testing (PT) records (i.e. CMS CASPER Reports 0155D entitled, "Individual Laboratory Profile" and CMS CASPER Report 0153D entitled, "Unsuccessful (2 of 3) Report"), it was determined that the laboratory failed to successfully participate in a PT program approved by CMS for each analyte or test in which the laboratory is certified under CLIA. The findings included: The laboratory failed to achieve satisfactory overall testing event score in two out of three consecutive testing events in the specialty of Bacteriology, constituting unsuccessful PT performance. (See D2028)

D2028	BACTERIOLOGY CFR(s): 493.823(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on desk review of CMS PT records (CMS CASPER Report 0155D and 0153D, it was determined that the laboratory failed to achieve satisfactory performance in two out of three consecutive PT events for Bacteriology, resulting in an "initial" (first) unsuccessful performance. The findings include: a. The laboratory failed to maintain successful performance by failing to maintain a score of 80% of acceptable responses in two out of three consecutive PT events for Bacteriology, as follows: 2019 Q3 2020 Q1 Bacteriology 75% 75% Q1 = First Testing Event Q3 = Third Testing Event b. Failure to achieve satisfactory performance in two out of three consecutive PT resulted in an initial unsuccessful performance for Bacteriology.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing: Laboratory director was not met. The laboratory director, high complexity testing, failed to ensure that PT samples were tested as required under Subpart H of this part. (See D6089)
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on a desk review of CMS PT records, it was determined the laboratory director, high complexity testing, failed to ensure that PT samples were tested as required under subpart H. of this part. The findings included: For Bacteriology, the laboratory repeatedly failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events, resulting in unsuccessful PT performance. (See D2016 and D2028)