

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0580198	(X3) Date Survey Completed 02/06/2020
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
D2066	<p>SYPHILIS SEROLOGY CFR(s): 493.835(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing result reports, and interview with the laboratory consultant, and the laboratory personnel, it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent was unsatisfactory performance. The findings included: a. The laboratory performed RPR using ASI card test kit and enrolled its proficiency testing program with American Association of Biocatalysts (AAB). b. The laboratory attained an overall PT testing event score of 0% for RPR in the Q3 2019 AAB PT event which was unsatisfactory performance. c. The laboratory performed RPR in approximately 110 patient specimens monthly. d. The laboratory technical consultant affirmed (2/5/2020 @ 1:45 PM) that the laboratory attained an overall PT testing event score of 0% for RPR in the Q3 2019 AAB PT event which was unsatisfactory performance.</p>
D2075	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing result reports, and interview with the technical consultant and the laboratory personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for</p>

Antinuclear antibody (ANA), Antistreptolysin (ASO), Rheumatoid Factor (RF), and Rubella (RB) in each testing event was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed general immunology testing including ANA, ASO, RF, RB. b. The laboratory participated AAB proficiency testing programs to evaluate the proficiency testing performance of the above mentioned testing. c. The laboratory attained 0% for ANA, ASO, RF, and RB in the Q3 2019 AAB PT event, which was unsatisfactory analyte performance for the testing event. d. the laboratory performed in approximately 45 patient samples each for ANA, ASO, RF, and RB testing. e. The laboratory technical consultant affirmed (2/6/2020 @ 1:35 PM) that the laboratory attained scores of 0 % for ANA, ASO, RF, and RB in the Q3 2019 AAB PT event, which was unsatisfactory analyte performance for the testing event.

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 review of the laboratory proficiency testing result reports, and interview with the laboratory technical consultant and the laboratory personnel, it was determined that the laboratory failed to, at least twice annually, verify the accuracy of any test or procedure it performed those are not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory performed Total Microalbumin (TM), Urine pH (pH), Urine Creatinine (UC), Growth Hormone (GH), Homocysteine (HC), Total Lipo A (LpA), Retic (Rc), which are not listed in the subpart I of 42 CFR part 493. b. The analyte mentioned above are not required to participate proficiency testing programs approved by CMS. However, it is required, at least twice annually, the laboratory must verify the accuracy of any test or procedure the laboratory performs. c. The laboratory, in order to verify the accuracy of the testing, elected to enroll with American Association of Bioanalysts (AAB) PT programs. d. The laboratory attained scores of 0 % for GH testing in the Q1, 2019 and TM testing in the Q3, 2019 AAB PT events which were unsatisfactory performance. e. The laboratory attained scores of 50 % and 0 % for HC testing in the Q1, 2019 and in the Q3, 2019, AAB PT events, respectively, which were unsatisfactory performance. f. The laboratory attained scores of 60 % and 0 % for LpA testing and RC, respectively in the Q3, 2019 AAB PT events, which were unsatisfactory performance. h. The laboratory performed GH and TM g.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of the laboratory proficiency testing result reports, and interview with the technical consultant and the laboratory personnel, it was determined that the laboratory director failed to ensure that the proficiency testing results scoring at least 80% grade for ANA, ASO, RF, and RB in the Q3 2019 AAB PT event. The findings included: a. The laboratory director failed to ensure the the laboratory to attain at least 80 percent of acceptable responses for each analyte in each testing PT event was unsatisfactory analyte performance. b. The laboratory attained 0% scores for ANA, ASO, RF, RB & RPR in the Q3 2019 AAB PT, which were unsatisfactory performances (see D-2066 and D-2075)

D6023

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(6)

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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:

Based on review of the laboratory proficiency testing result reports, and interview with the laboratory technical consultant, and the laboratory personnel, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for TM, pH, UC, GH, HC, LpA, and RC testing systems. The findings included: a. The laboratory failed to verify the accuracy of analyte, including, but are not limited to the followings: TM, GH, HC ..(see D-5217).