

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0580198	<b>(X3) Date Survey Completed</b>  02/14/2022
<b>Name of Provider or Supplier</b>  Advanced Biomedical, Inc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on touring the laboratory facility, review of the laboratory Protime (PT)/INR records, observe the digital thermometer (DT) device and review of temperature records, and interview with the laboratory testing personnel, it was determined that the laboratory failed to perform following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system. The findings included: A a. The laboratory performed Protime (PT) coagulation testing and report INR ratio, which was a calculated result by <math>INR = (PT \text{ test} / PT \text{ normal}) \text{ ISI}</math>; where <math>INR = \text{International Normalized ratio}</math> <math>PT \text{ test} = \text{tested prothrombin time}</math> <math>PT \text{ normal} = \text{normal prothrombin time (mean)}</math> <math>ISI = \text{international sensitivity index}</math> b. The laboratory's policy and procedure for "PT -INR Adjustment Ratio" (page 3/3) item 4. "To determine the mean normal PT for the new thromboplastin, please perform the following: a. Run at least 6 normal patients in duplicates for PT studies and record the average "seconds" on the "PATIENT MEAN OF NORMAL" sheet. c. The laboratory failed to follow its written policy and procedure to run 'duplicates" in the new PT normal mean in 2/20/2020. B a. The laboratory failed to perform following the manufacturer's instructions of a DT device, and in a manner that provides test results within the laboratory's stated performance specifications. b. The laboratory used refrigerators and freezers to store the laboratory reagents, supplies, patient samples for the validity, stability, and quality of the laboratory testing systems. c. The laboratory used digital temperature (DT) thermometer to monitor the temperatures to maintain the storage conditions within the</p>

laboratory established acceptable temperature ranges, 2 to 8 degrees Celsius for refrigeration. c. The DT features an Alarm on/off, Lo/Hi for acceptable (optimal) temperature range for storage of reagents etc. and Min/Max to indicate the temperature conditions while the laboratory was closed. d. On the date of survey (2/14/2022 @ 11:45 am) an DT Alarm was off and when turned on, the alarm went off, which indicated at sometimes past, the storage temperature conditions was out of the acceptable temperature range. e. The laboratory failed to document any corrective action taken due to the temperature was once out of the acceptable range.

**D5441**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory quality control (QC) records, and interview with the laboratory personnel, it was determined that the laboratory failed to establish the quality control procedures to monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance and to ensure the accuracy, reliability and timely of the patient testing results and reports, and document all control procedures performed. The findings included: a. The laboratory used Roche Cobas 8000 to perform routine chemistry including, but are not limited to Alkaline Phos (ALP), Glucose etc. b. The Levey-Jennings (LJ) would indicate any trending or shifting for the testing system so to assure the accuracy and reliability of the analytic process. c. Review its LJ QC charts from 6/1/2022 to 6/30/2022 for the routine chemistry panel with the QC level 1 lot # 423926 expiry of 2/28/2022 and QC level 2 lot #423932 expiry of 2/28/2022. d. The LJ charts for ALP QC level 1 indicated that the 19 out of 24 daily QC from 6/1/22 to 6/30/22 the QC daily were between +1SD and +2 SD and one out of the 19 was > +2SD above the mean (positive bias). e. The LJ charts for ALP QC level 2 indicated that the 20 out of 23 daily QC from 6/1/22 to 6/30/22 the QC daily were between +1SD and +2 SD above the mean (positive bias). f. The laboratory failed to document of any corrective actions taken for shifting bias of the above item d & e. g. The laboratory personnel affirmed (2/14/2022 @ 12:25 pm) that no actions were taken to assure the accuracy and reliability of the testing system and failed to document the analytic systems activities.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on touring the laboratory facility, review of the laboratory's quality control (QC) records, Protime (PT)/INR records, observe the digital thermometer (DT) device and review of temperature records, and interview with the laboratory testing personnel, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. The findings included: a. The laboratory performed routine chemistry, Protime (PT) coagulation with INR ratio. b. The laboratory failed to follow its established policy and procedure to obtain the PT normal mean in 2/20/2020 for the calculation of INR ratio, see D-5411 A. c. The laboratory failed to familiarize a digital thermometer (DT) feature, and follow the manufacture instruction in a manner that always assure the temperature conditions in the storage devices within the established acceptable temperature range, see D-5411 B d. The laboratory failed to document of any corrective actions taken while review the Levey-Jennings charts for shifting obias or trending of the series of quality control data, see D-5441

**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 touring the laboratory facility, review of the laboratory's quality control (QC) records, Protime (PT)/INR records, observed the digital thermometer (DT) device and review of temperature records, and interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. The findings included: a. The laboratory performed routine chemistry, and Protime (PT) coagulation test with INR ratio. b. The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system, see D-5411 A & B, D-5441 and D-5791