Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2069499	07/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Allcells Buyer Corp	1640 S Loop Rd, Ste 250, Alameda, 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
D2122	HEMATOLOGY CFR(s): 493.851(b) (b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of AAB-Medical Laboratory Evaluation proficiency testing (PT) records, review of four (4) randomly selected patients ranging from 12/12/2022 to 2/17/2025 and interview with the testing personnel (TP); the laboratory failed to attain an overall testing event score of at least 80 percent which is unsatisfactory performance. The findings included: 1. On the date of the survey 07/17/2025 at approximately 11:00 a.m. based on review of the PT scores, the laboratory obtained for Hematology third proficiency event for the year 2024 (Q-3 2024) an overall score of 60% for Platelets. 2. The TP affirmed on 7/17/2025 at approximately 11:15 a.m. the laboratory obtained the PT score of 60% for Q3-2024 for platelets count. 3. According to the laboratory testing declaration submitted on the day of the survey (07/17/2025, the laboratory performed approximately 833 samples (quarterly) during the time the laboratory received an unsatisfactory PT performance score.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on the surveyors' review of the laboratory's policies & procedures, four (4)

	randomly selected patients' test records, and interview with the laboratory's Quality Director (QD) and testing personnel (TP); the laboratory failed to establish and follow written policies and procedure to assess quality of its preanalytical, analytic, and postanalytic systems. The findings include: 1. The laboratory did not have a system in place to identify problems in the phases of laboratory testing: preanalytical, analytic, and postanalytic system such as test request, testing results, and final report. When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification, immediate resolution of the problem, and development of policies that will prevent its recurrence. 2. The QD and TP on the day of the survey at approximately 12:30 p.m., affirmed that the laboratory did not establish and follow preanalytic, analytic, and postanalytic systems quality assessment policies and procedures. 3. The laboratory's testing declaration form signed by the laboratory director on 07/17/2025 stated that the laboratory performed approximately 2,500 tests annually.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment 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 the surveyor's findings on July 17, 2025, the laboratory director is herein cited for the deficient practice of failure to ensure quality assessment programs were completely established and followed to assure and monitor the quality of laboratory services provided, and to identify issues as it occured. See D5391.