Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2126670	12/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Allcells, Llc	1250 Hancock St, Quincy, MA	

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
D0000	A CLIA paper desk review of proficiency testing was conducted for the the AllCells, LLC laboratory on 12/09/2024 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR493. Based on evidence of unsuccessful proficiency testing performance for the Hematology Hematocrit analyte, the following Condition level deficiencies were deemed to be not met: D2016 - 42 C.F.R. 493.803 Condition: Successful Participation, Proficiency Testing D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director .
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 calendar year 2024 proficiency testing review (three testing events) of the American Association of Bioanalysts proficiency testing program the laboratory failed to attain a testing event score of at least 80 percent for the Hematology Hematocrit analyte leading to unsatisfactory performance. The laboratory received an overall testing score for the Hematology Hematocrit analyte of 20 percent for the first testing event of 2024 and a score of 0 percent for the third testing event of 2024. Refer to D2128 and D2130 .
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: . Based on calendar year 2024 proficiency testing review (three testing events) of the American Association of Bioanalysts proficiency testing program results, the laboratory failed to undertake remedial action in response to unsatisfactory proficiency testing events as evidenced by the following: The laboratory achieved a Hematocrit analyte score of twenty (20) percent for the first testing event of 2024 and a score of zero (0) for the third testing event of 2024 resulting in an unsatisfactory performance for each of the testing events and overall unsuccessful performance for the analyte (refer to D2130). Based on the second unsatisfactory testing event score there was no assurance that appropriate training had been undertaken, and technical assistance employed, to correct the problems associated with proficiency testing failures. .
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: . Based on calendar year 2024 proficiency testing review (three testing events) of the American Association of Bioanlaysts proficiency testing program results, the laboratory failed to achieve satisfactory performance for the same analyte for two out of three consecutive proficiency testing events as evidenced by the following: The laboratory achieved a Hematocrit analyte score of twenty (20) percent for the first testing event of 2024 and a score of zero (0) for the third testing event of 2024 resulting in an unsatisfactory performance for each of the testing events and overall unsuccessful performance for the analyte. .
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on the deficiencies cited herein, the laboratory director failed to ensure that effective remedial action was instituted in response to unsatisfactory proficiency testing results resulting in the second unsuccessful performance for the Hematocrit analyte in the specialty of Hematology. Refer to D2016, D2128, and D2130.