Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2252893	11/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Allcells, Llc	3509 Elgin Street Suite 300, Houston, TX	

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	The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel; Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the review of the manufacturer's instructions, the laboratory's records from July 2022 to Oct 2022, and confirmed in an interview found the laboratory failed to document the operating room temperature, the laboratory's humidity, and the refrigerator temperature stored QC materials for four of four months on one of one Horiba Micro60 hematology analyzer. The findings were: 1. Review of the manufacturer's user manual titled Horiba Medical ABX Micro60 Hematology Analyzer User Manual (Ref: RAB043MUS) under 2.2. Operating Temperature /Humidity revealed: "18 to 32C (65 to 90F) Maximum relative Humidity, 80% for temperatures up to 31C (88F) decreasing linearly to 50% relative humidity at 40C (104F)." 2. Review the manufacturer's instructions titled Horiba Medical QC

	information sheet under 5. Stability and storage revealed "Store the tubes vertically in their original package at 2 to 8C (35 to 46F) when not in use." 3. Review of the laboratory's records from July 2022 to Oct 2022 revealed no documentation of the operating temperature, the laboratory's humidity, and refrigerator's temperature where QC materials were stored for four of four months reviewed. 4. Review of patient results from July 2022 to October 2022 revealed the following: 7/4/2022 to 7/27/2022 Total of 46 patients had CBC testing. 8/1/2022 to 8/30/2022 Total of 83 patients had CBC testing. 9/1/2022 to 9/26/2022 Total of 95 patients had CBC testing. 10/3/2022 to 10/31/2022 Total of 77 patients had CBC testing. 4 An interview with the Vice President (VP), clinical operations on 11/8/2022 at 12:15 pm in an office confirmed the above findings. Key: QC=Quality Control
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 the review of the laboratory's records from July 2022 to October 2022, patient results from July 2022 to October 2022, and confirmed in an interview found the laboratory failed to have a method in place to monitor quality control values over time to detect shifts and trends for one of one Horiba Micro60 hematology analyzer for four of four months. The findings were: 1. Review of the laboratory's records revealed the laboratory had no written control procedure that monitor the accuracy and precision of the complete analytic process. 2. Further review of the laboratory's records from July 2022 to October 2022 revealed the laboratory did not have a method in place to monitor quality control values over time to detect shifts and trends for one of one Horiba Micro60 hematology analyzer (MSN:108CS99795) for four of four months. 3. Review of patient results from July 2022 to October 2022 revealed the following: 7/4/2022 to 7/27/2022 Total of 46 patients had CBC testing. 8/1/2022 to 8 /30/2022 Total of 83 patients had CBC testing. 9/1/2022 to 9/26/2022 Total of 95 patients had CBC testing. 10/3/2022 to 10/31/2022 Total of 77 patients had CBC testing. 4. An interview with the Vice President (VP), clinical operations on 11/8/2022 at 12:00 pm in an office confirmed the above findings. Key: QC=Quality Control CBC=Complete Blood Count
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive

	maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the manufacturer's user manual, the laboratory's reagent logs from July 2022 to October 2022, Patient results, and confirmed in an interview found the laboratory failed to document a quality control run after a change in a reagent on one of one Horiba Micro60 hematology analyzer for one of five days reviewed. The findings were: 1. Review of the manufacturer's user manual titled Horiba Medical ABX Micro60 Hematology Analyzer User Manual (Ref: RAB043MUS) under 1.5 Reagents revealed "3 Reagents or 1 Pack of Reagents Diluent Cleaner Lyse 2. Review of the laboratory's reagent logs from July 2022 to OCT 2022 revealed no documentation of the quality control run after the following reagent change for one of five days reviewed on one of one Horiba Micro60 hematology analyzer (SN: 108CS99795). 9/26/2022 at 9:20 am Lyse Lot# 211220S3 Exp: 12/20/2022 3. Review patient results for 9/26/2022 revealed 3 patients had CBC testing after the reagent was changed. 9/26/22 Donor ID: 53548 at 10:08 am 9/26/22 Donor ID: 49912 at 11:49 am 9/26/22 Donor ID: 53765 at 2:26 pm 4. An interview with the Vice President (VP), clinical operations on 11/8/2022 at 12:13 pm in an office confirmed the above findings. Key: CBC=Complete Blood Count
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on the review of the laboratory's submitted CMS 209, testing personnel records, and confirmed in an interview found the laboratory failed to have educational equivalent documentation to qualify one of three testing personnel (TP) who performed moderate complexity testing on Horiba CBC analyzer. (Refer to 6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by:

	Based on the review of the laboratory's submitted CMS 209, testing personnel records, and confirmed in an interview found the laboratory failed to have educational equivalent documentation to qualify one of three testing personnel (TP) who performed moderate complexity testing on Horiba CBC analyzer. The findings were: 1. Review of the laboratory's submitted CMS 209 identified three TP who performed moderate complexity testing on one of one Horiba Micro60 hematology analyzer (SN: 108CS99795). 2. Review of the laboratory's TP educational records revealed the laboratory failed to have documentation of educational equivalency to qualify one of three TP who obtained the educational degree from outside of United States. TP#3 Hired Date 02/28/2022 3. An interview with the Vice President (VP), clinical operations on 11/8/2022 at 9:45 am in an office confirmed the above findings. The VP found out the TP #3 had educational degree from outside the United States and did not have equivalent check via the company. Key: CMS=Center of Medicare and Medicaid Services CBC=Complete Blood Count