Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0283906	10/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cell Science Systems Corporation	852 S Military Trail, Deerfield Beach, FL	

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	An announced CLIA recertification survey was conducted at CELL SCIENCE SYSTEMS CORPORATION from September 23, 2025 to October 24, 2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory failed to complete the performance specification verification for the Cellular Micronutrient Assay (CMA) test before patient testing since 08/28/2025. Finding included: 1-During the laboratory tour on 09/23/2025 at 10:30 AM, the surveyor observed that the laboratory used for CMA test the Biotek epoch2 spectrophotometer with identification number ST-760. 2-Review of the revalidation of the CMA performance specification verification study performed by the laboratory revealed that in the Validation Worksheet the laboratory listed that used a Microplate reader (spectrophotometer to read at 490 nm with a reference filter of 650nm) Epoch2 with identification ST-228 (Biotek). 3-Review of the revalidation Standard Operation Procedure (SOP) signed by the laboratory Director on 08/28/2025 revealed that on page 7 the laboratory failed to identify the spectrophotometer used for the reading. 4-The laboratory tested 716 until 09/23/2025 since the implementation on 08/28/2025. 5-During an interview on 09/23

	/2025 at 1:00 PM, the General Supervisor acknowledged that the laboratory failed to compare the readings between the spectrophotometer used for Validation (ST-228) and the one used for patients (ST-760).
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to-- (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Supervisor (TS) or a designee failed to do direct observation of patient testing during competency evaluation for 2 Testing Personnel (TP) out of 12 in 2025. Findings included: 1-Review of FORM CMS 209 signed by the Laboratory Director on 09/22/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant. The laboratory had a Technical Supervisor who was also the General Supervisor (GS) for Chemistry, Immunology and Histocompatibility specialties. The laboratory had 12 testing personnel (GS/TP1, TP2, TP3, TP4, TP5, TP6, TP7, TP8, TP9, TP10, TP11, and TP12). 2-Review of personnel records initial competency for TP8 revealed that the direct observation of patient testing with the ROBOCAT in the Immunology specialty, was observed by TP11 on 04/01/2025. TP11 had no delegation letter to do competency. 3- Review of personnel records annual competency for TP12, revealed that the direct observation of patient testing with the ROBOCAT in the Immunology specialty, was observed by TP11 on 05/20/2025. TP11 had no delegation letter to do competency. 4- During an interview on 09/23/2025 at 3:42 PM, the Quality Assurance manager confirmed that TP11 did not have a delegation to perform the patient testing observation during competency for TP8 on 04/01/2025, and TP12 on 05/20/2025.
D6124	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iv) (b)(8)(iv) Direct observation of performance of instrument maintenance and function checks; This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Supervisor (TS) or a designee failed to do direct observation of performance of instrument and function check during competency evaluation 2 testing personnel (TP) out of 12 in 2025. Findings included: 1-Review of FORM CMS 209 signed by the Laboratory Director on 09/22/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant. The laboratory had a Technical Supervisor who was also the General Supervisor (GS) for Chemistry, Immunology and Histocompatibility specialties. The laboratory had 12 testing personnel (GS/TP1, TP2, TP3, TP4, TP5, TP6, TP7, TP8, TP9, TP10, TP11, and TP12). 2-Review of personnel records initial competency for TP8 revealed that the direct observation of performance of instrument and function check during competency with the ROBOCAT in the Immunology specialty, was observed by TP11 on 04/01/2025. TP11 had no delegation letter to do competency. 3-Review of personnel records annual competency for TP12, revealed that the direct observation of performance of instrument and function check during competency with

	the ROBOCAT in the Immunology specialty, was observed by TP11 on 05/20/2025. TP11 had no delegation letter to do competency. 4- During an interview on 09/23 /2025 at 3:42 PM, the Quality Assurance manager confirmed that TP11 did not have a delegation to direct observation of performance of instrument and function check during competency for TP8 on 04/01/2025, and TP12 on 05/20/2025.