Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0932073	10/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hitachi Chemical Advanced Therapeutics Solutions	4 Pearl Court Suite C, Allendale, NJ	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: a. Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to maintain the Attestation Statements (AS) signed by the analyst and laboratory director for Hematology and Stem Cell Processing (SCP) tests performed with the College of American Pathologists in B and C-2018 and A-2019 events. The findings include: 1. The laboratory did not maintain the AS for: a. Hematology FH2-B 2018, FH2-C 2018 and FH2-A 2019 b. SCP-A-2019. 2. The LD confirmed on 10/3/19 at 11:15 am that the laboratory did not maintain all AS records. b. Based on surveyor review of PT records and interview with the LD, the laboratory failed to retain all PT result records performed with the CAP in Hematology FH2-B 2018 and SCP-B 2019 events. The LD confirmed on 10/3/19 at 11:40 am that all PT records were not retained.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)

	The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to review and evaluate PT results obtained from the College of American Pathologists (CAP) for Hematology and Stem Cell Processing (SCP) events performed in 2018 and 2019. The findings include: 1. There was no evaluation documented when the laboratory received exception code 20 - No appropriate target/response cannot be graded for SCP-A 2019 White Blood Cell Count samples SCP-01 and SCP-02. 2. There was no evaluation documented when the laboratory received exception code 26 - Educational Challenge for Blood Cell Identification and SCP as follows: a. FH2 A-2018 samples BCP-16 through BCP-20 b. FH2 C-2018 samples BCP-26 through BCP-30 c. SCP A-2018 - Number of CD45 + Events D, %CD3 + Dual, Calc Absolute CD3 Dual, Number of CD34+ Single, % CD+ Single, , CD 34 Viability %, Calculation of CD34/kg, Calculation of CD3/kg. Samples SCP-01 and SCP-02. d. SCP B-2018 - Number of CD45 + Events D, %CD3 + Dual, Calc Absolute CD3 Dual, Number of CD34+ Single, %CD+ Single, , Total NC Viability %, CD 34 Viability %, Calculation of CD34/kg, Calculation of CD3/kg. SCP-03 and SCP-04 e. SCP A-2019 - Number of CD45 + Events D, %CD3 + Dual, Calc Absolute CD3 Dual, Number of CD34+ Single, %CD+ Single, , CD 34 Viability %, Calculation of CD34/kg, Calculation of CD3/kg. SCP-01 and SCP-02 3. There was no evaluation documented when the laboratory received exception code 30 - Scientific Committee decision for SCP-B 2018 samples SCP-03 and SCP-04 for: a. White Blood Cell Count b. Absolute #CD34 Calc S c. Total NC Viability % 4. The LD confirmed on 10/3/19 at 10:45 am that the laboratory did not review and evaluate all PT results.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Laboratory Director (LD), the Testing Personal failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Beckman Act Diff and FACS Caliber analyzer from 10/30/17 to the date of the survey. The LD confirmed on 10/3/19 at 1:45 pm that trends and shifts were not reviewed.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or

	continuing education to improve skills. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the LD failed to establish a Competency Assessment (CA) procedure with all the required elements for Testing Personnel from 10/30/17 to the date of survey. The LD confirmed on 10/3/19 at 11:30 am that a CA procedure was not established.