Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1022793	08/21/2025
Name of Provider or Supplier	**Street Address, City, State**	
Creative Testing Solutions	5700 Pleasant View Road, Memphis, TN	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the laboratory procedure manual, a review of calibration verification documents, a lack of documentation, staff interview, and electronic mail (email) communication, the laboratory failed to follow the procedure for performing calibration verification at least every six months for the Alanine Aminotransferase (ALT) and Total Protein (TP) donor testing performed on the Abbott Architect C8000 instrument in 2024 and 2025, with a total of 320,528 ALT assays and 88,181 TP assays performed during the gaps in calibration verification. The findings include: 1. Laboratory observation on 08/20/25 at 9:15 a.m. revealed two Abbott Architect C8000 instruments used for performing ALT and TP on samples from plasma donors. 2. A review of the laboratory policy titled "ABBOTT ARCHITECT C8000 MAINTENANCE, CALIBRATION AND ADMINISTRATION" in section 5.4 titled "PROCEDURE-SEMI-ANNUAL LINEARITY/CALIBRATION VERIFICATION" revealed that "Linearity / Calibration Verification is to be performed at least once every six months according to laboratory schedule." 3. A review of the laboratory's calibration verification documentation for the ALT and TP assays performed on the Abbott Architect C8000 revealed the following dates when calibration verification for the ALT and TP was performed: ALT = 01/04/24, 10/11/24, 05/02/25 TP = 11/28/23, 10/11/24, 05/02/25 There was no documentation that calibration verification was performed for the ALT assay when it was due in July 2024 or in April 2025. There was no documentation that calibration verification was performed for the TP assay when it was due in May 2024

	or in April 2025. 4. The Director of Operations confirmed the survey findings during an interview on 08/21/25 at 11:15 a.m. 5. A review of an email communication received from the Quality Site Manager on 09/03/25 at 7:21 a.m. revealed that a total of 320,528 ALT assays and a total of 88,181 TP assays were performed during the gaps in calibration verification.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on laboratory observation and staff interviews, the laboratory failed to label two of two controls used on the Abbott Architect C8000 that had been poured from the primary control bottle to a secondary container. The findings include: 1. Laboratory observation of the Abbott Architect C8000 area on 08/21/25 at 12:20 p.m. revealed two liquids in an instrument sample rack sitting in a tray in the refrigerator. The containers were not labeled. Testing person ten stated during the observation that the liquids in the rack were two levels of controls that were used on the Abbott Architect C8000 to perform quality control testing for the ALT and TP analytes. 2. The Director of Operations confirmed the survey findings during an interview on 08 /21/25 at 12:26 p.m.
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: CITATION NUMBER ONE: Based on laboratory observation, review of validations, lack of documentation, staff interviews, and review of an electronic mail (email) communication, the laboratory failed to verify the manufacturer's performance specifications for precision for the revised Hepatitis C Virus (HCV) antibody test with approximately 2,074,613 donor tests performed since testing began on 08/19/24. The findings include: 1. Laboratory observation on 08/20/25 at 9:15 a.m. revealed multiple Abbott Alinity s instruments used for performing donor testing for HCV Antibody, Human Immunodeficiency Virus (HIV) Antigen and Antibody, Hepatitis B Surface Antigen (HBsAg) and Hepatitis B Surface Antigen (HBsAg) confirmatory testing. 2. A review of validations performed for a revised HCV Antibody method, approved for use on 08/19/24, revealed no documentation that the laboratory had verified the precision of the method in their laboratory. 3. The Director of Operations confirmed

	the survey findings during an interview on 08/21/25 at 3:30 p.m. 4. The Director of Operations stated during a phone interview on 08/28/25 at 2:00 p.m. that the revised HCV assay was put into use for donor testing on 08/19/24. 5. A review of an email received on 08/28/25 at 3:45 p.m. from the Director of Operations revealed the total number of donor samples tested from the date the revised HCV antibody was put into use until the date of the survey was approximately 2,074,613. CITATION NUMBER TWO: Based on laboratory observation, a review of instrument validation data, and staff interviews, the laboratory failed to verify the manufacturer's claims for precision for the tests performed on two of two new Abbott Alinity s instruments put into use since the last survey date. The findings include: 1. Laboratory observation on 08/20 /25 at 9:15 a.m. revealed multiple Abbott Alinity s instruments used for performing donor testing for HCV Antibody, HIV Antigen and Antibody, HBsAg and HBsAg confirmatory testing. 2. A review of the instrument and method validations for serial numbers 1436 and 1437 revealed that the validation data had not been evaluated to verify laboratory performance for precision. 3. The Director of Operations confirmed the survey findings during an interview on 08/21/25 at 3:30 p.m. 4. The Director of Operations stated during a phone interview on 08/28/25 at 2:00 p.m. that instrument serial number 1436 was put into use on 05/03/24 and instrument serial number 1437 was put into use on 05/07/24.