

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0957496	(X3) Date Survey Completed 06/26/2025
Name of Provider or Supplier Creative Testing Solutions	Street Address, City, State 4401 Freidrich Lane Building 1 Suite 105, Austin, 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 surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by:</p> <p>I. Based on review of calibration records, quality control records, and interview, the laboratory failed to retain all calibration records on the Abbott Laboratories Alinity s System for HIV Ag/Ab (Human Immunodeficiency Virus Types 1 and 2) for two of 20 calibrations reviewed over 5 random months of testing on 5 random single analyzers. Findings follow. A. Review of the Alinity s Calibration Detail Reports for HIV Ag/Ab from 10/06/2023 - 10/31/2023 (serial number 1353), 06/25/2024 - 07/24/2024 (serial number 1359), 11/22/2024 - 12/27/2024 (serial number 1358), 02/07/2025 - 02/26/2025 (serial number 1352), and 04/10/2025 - 04/29/2025 (serial number 1351) showed no calibration reports for 1) 07/10/2024 (serial number 1359) and 2) 11/22/2024 (serial number 1358). B. Review of the QC Result Details Report for HIV Ag/Ab showed the calibrations were performed on 07/10/2024 and 11/22/2024 but was lacking the specific calibration data found on the Calibration Detail Report. C. Interview with the Quality Assurance Supervisor on June 25, 2025 at 1530 hours in the conference room confirmed there were missing calibration reports. II. Based on review of calibration records, quality control records, and interview, the laboratory failed to retain all calibration records on the Abbott Laboratories Alinity s System for</p>

HBsAg (Hepatitis B Surface Antigen) for two of 20 calibrations reviewed over 5 random months of testing on 5 random single analyzers. Findings follow. A. Review of the Alinity s Calibration Detail Reports for HBsAg from 10/06/2023 - 10/31/2023 (serial number 1353), 06/25/2024 - 07/24/2024 (serial number 1359), 11/22/2024 - 12/27/2024 (serial number 1358), 02/07/2025 - 02/26/2025 (serial number 1352), and 04/10/2025 - 04/29/2025 (serial number 1351) showed no calibration reports for 1) 07/10/2024 (serial number 1359) and 2) 11/22/2024 (serial number 1358). B. Review of the QC Result Details Report for HBsAg showed the calibrations were performed on 07/10/2024 and 11/22/2024 but was lacking the specific calibration data found on the Calibration Detail Report. C. Interview with the Quality Assurance Supervisor on June 25, 2025 at 1530 hours in the conference room confirmed there were missing calibration reports. III. Based on review of calibration records, quality control records, and interview, the laboratory failed to retain all calibration records on the Abbott Laboratories Alinity s System for Anti-HCV (antibodies to Hepatitis C virus) for two of 20 calibrations reviewed over 5 random months of testing on 5 random single analyzers. Findings follow. A. Review of the Alinity S Calibration Detail Reports for Anti-HCV from 10/06/2023 - 10/31/2023 (serial number 1353), 06/25/2024 - 07/24/2024 (serial number 1359), 11/22/2024 - 12/27/2024 (serial number 1358), 02/07/2025 - 02/26/2025 (serial number 1352), and 04/10/2025 - 04/29/2025 (serial number 1351) showed no calibration reports for 1) 07/10/2024 (serial number 1359) and 2) 11/22/2024 (serial number 1358). B. Review of the QC Result Details Report Anti-HCV showed the calibrations were performed on 07/10/2024 and 11/22/2024 but was lacking the specific calibration data found on the Calibration Detail Report. C. Interview with the Quality Assurance Supervisor on June 25, 2025 at 1530 hours in the conference room confirmed there were missing calibration reports.