

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2002212	(X3) Date Survey Completed 09/02/2026
Name of Provider or Supplier Valley Day And Night Clinic	Street Address, City, State 1214 Dixieland Rd Ste 8, Harlingen, 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
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 review of the manufacturer's instructions for the Boule Con-Diff Tri-Level controls, surveyor observation of control material currently in use, and staff interview, the laboratory failed to document the revised expiration dates for 3 of 3 controls. The findings included: 1. The manufacturer's instructions for the Boule Con-Diff Tri-Level controls (201043L, R03.31.15) under the section titled "Storage and Stability" stated: "Open vial stability 14 days after opening when returned to refrigerator after each use." 2. Surveyor observation of control material currently in use on 09/02/2026 at 1055 hours in the laboratory identified 3 levels of control material with an opened date on 08/29/2026. The controls were not labeled with the revised expiration date 14 days from the open date. The quality control materials were: a) Low control Lot number: 22606-31 b) Normal control Lot number: 22026-32 c) High control Lot number: 22026-33 3. The testing person stated the control were good for 3 months or until the original expiration of the vial in an interview conducted on 09/02/2026 at 1100 hours in the laboratory. She was unaware of the 14 day revised expiration once opened. This confirmed the findings.