Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1047501	04/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Valley Day And Night Clinic	1755 W Price Rd, Brownsville, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's maintenance records, and staff interview, it was revealed that the laboratory failed to have documentation of performing the required weekly maintenance procedures on the Vitros 350 chemistry analyzer for four of four weeks in September 2022. Findings include: 1. A review of the laboratory's policy titled 'Instrument Operation and Maintenance' revealed the following: "Maintenance of each piece of laboratory instrumentation shall be in accordance with the manufacture's recommendations. Document all maintenance performed on the test systems in use." 2. A review of the laboratory's maintenance records for the Vitros 350 chemistry analyzer revealed the laboratory failed to have documentation of performing the following required weekly maintenance procedures for all 4 weeks in September 2022: - Clean tray platform and transport arm - Clean cup retainer - Clean diluent bottles - Clean tip locator assembly - Clean control unit screen - Clean keypad cover - Inspect, clean, and/or replace air filter - Back up QC /Config/Calibration Data 3. An interview with the technical consultant (as indicated on the CMS 209 form) on 4/27/23 at 9:40 a.m. in the conference room, after review of the records, confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's quality control and calibration records, calibration verification (linearity) records for the Vitros 350 chemistry analyzer from 2022, and staff interview, it was revealed that the laboratory failed to have documentation of performing two of two calibration verification procedures in 2022 for the analyte T3 Uptake tested on the Vitros 350 analyzer. Findings include: 1. A review of the laboratory's quality control and calibration records for the Vitros 350 analyzer revealed T3 Uptake was calibrated using 2 calibrators and the laboratory tested 2 levels of quality control once a day, thus calibration verification was required at least every 6 months. 2. A review of the calibration verification records from 2022 revealed the laboratory failed to have documentation of performing calibration verification procedures, every 6 months, for T3 Uptake tested on the Vitros 350 analyzer. 3. An interview with the technical consultant (as indicated on the CMS 209 form) on 4/27/23 at 10:30 a.m. in the conference room, after review of the records, confirmed the above findings.