Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1047501	12/15/2021
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 representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS Form 209, review of manufacturer's instructions, review of laboratory personnel records, patient records, and confirmed in interview of laboratory personnel, the laboratory failed to follow the manufacturer's instructions to ensure 7 of 24 testing personnel were trained prior to patient testing using Quidel's Quickvue SARS-COV-2 test kit under Emergency Use Authorization (EUA). The findings included: 1. Review of the laboratory's submitted CMS Form 209 approved by the laboratory director on December 15, 2021 found the laboratory listed 24 testing persons that performed SARS-COV-2 patient testing. 2. Review of the manufacturer's instructions for the Quidel Quickvue SARS-COV-2 test kit under

	Conditions of Authorization for the laboratory and patient care, it stated, "All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling." 3. Review of personnel records for the following 7 of 24 testing persons (as listed on CMS Form 209) performing SARS-COV-2 did not have documentation of training as required by the manufacturer: Testing Personnel 11 Testing Personnel 12 Testing Personnel 17 Testing Personnel 20 Testing Personnel 22 Testing Personnel 23 Testing Personnel 24 4. Review of patient records found the 7 of 24 testing persons performed SARS-COV-2 patient testing on the following days: Testing Personnel 11 Accession Number: 632637 SARS-COV-2 Result: Negative Testing Personnel 12 Accession Number: 631454 SARS-COV-2 Result: Positive Testing Personnel 17 Accession Number: 627979 SARS-COV-2 Result: Negative Testing Personnel 20 Accession Number: 631541 SARS-COV-2 Result: Negative Testing Personnel 22 Accession Number: 632620 SARS-COV-2 Result: Negative Testing Personnel 23 Accession Number: 632633 SARS-COV-2 Result: Negative Testing Personnel 24 Accession Number: 632704 SARS-COV-2 Result: 632704 5. The laboratory was asked to provide documentation of following the manufacturer's instructions to ensure testing persons were trained to perform SARS-COV-2 patient testing using the Quidel Quickvue test kit. No documentation was provided. 6. An interview with the technical consultant on December 15, 2021 at 10:30 hours in the conference room confirmed the findings. Key: SARS-COV-2 - Severe acute respiratory syndrome coronavirus 2 CMS - Centers for Medicare and Medicaid Services
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records and staff interview, the laboratory failed to have documentation of verifying new lots of control material prior to use. The findings included: 1. A review of the laboratory's quality control records from 2020 and 2021 revealed the following lot number in use for T3 Uptake, Total T4, and Thyroid Stimulating Hormone (TSH): a) low control 40381 40391 b) high control 40383 40393 2. The laboratory was asked to provide documentation of verifying each lot of control prior to it being placed into service. No documentation was provided. 3. An interview with the technical consultant on December 15, 2021 at 13:00 hours in the conference room found the laboratory did not verify new lots of control material for chemistry. She stated she does this for hematology but not for chemistry. This confirmed the findings.

D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of manufacturer's instructions, review of quality control records, and confirmed in interview with laboratory personnel, the laboratory's quality assurance program failed to identify when numbers for quality control reference ranges were entered incorrectly for 15 of 25 entries reviewed. The findings included: Note: The laboratory utilizes manufacturer means and ranges for BioRad Liquid Assayed Multiqual (levels 1 and 3) and BioRad Lyphochek Immunoassay Plus Control (levels 1 and 3). 1. Review of the laboratory's policy titled "Quality Assurance Plan" under Quality Control, it stated, "We will evaluate our quality control policy for calibration and control data for each test method use [sic] in the laboratory and determine...If personnel have taken appropriate corrective action when calibration and control values are out of range and/or violated the modified westgard rules." 2. Review of the manufacturer's reference ranges for BioRad Liquid Assayed Multiqual level 1 (lot # 45831) and level 3 (lot # 45833) found the following means: Level 1 Level 3 Albumin (g/dL) 2.17 4.05 Alkaline Phosphatase 38.6 248 ALT /SGPT 24.7 184 AST/SGOT 46.4 299 Bilirubin (direct) 0.022 1.16 Bilirubin (total) 0.570 7.40 Calcium 6.23 13.1 Carbon Dioxide 16.4 28.7 Chloride 78.3 124 Cholesterol (HDL) 19.5 63.4 Cholesterol (total) 97.1 281 Creatinine 0.793 7.06 Glucose 55.5 349 Potassium 2.62 7.73 Protein (total) 3.65 6.29 Sodium 116 161 Triglycerides 99.3 216 Urea Nitrogen (BUN) 12.9 63.2 3. Random review of the laboratory Levy-Jennings entries for the same lot numbers found the following discrepancies in mean values entered: Lot #45831 (level 1) Bilirubin, Direct: 0.055 (instead of 0.022) Cholesterol (HDL): 19.6 (instead of 19.5) Triglycerides: 99.2 (instead of 99.3) Lot #45833 (level 3) Alkaline Phosphatase: 248.5 (instead of 248) ALT: 183.5 (instead of 184) AST: 298.5 (instead of 299) Bilirubin (direct): 1.158 (instead of 1.16) Calcium: 13.05 (instead of 13.1) Cholesterol (HDL): 63.5 (instead of 63.4) Cholesterol (total): 280.5 (instead of 281) Creatinine: 7.055 (instead of 7.06) Sodium: 160.5 (instead of 161) Total Protein: 6.30 (instead of 6.29) Triglycerides: 216.5 (instead of 216) Urea Nitrogen (BUN): 63.3 (instead of 63.2) 4. The laboratory's quality assurance program failed to identify that some entries for the mean of controls matched the manufacturer and others did not. 5. An interview with the technical consultant on December 15, 2021 at 13:30 hours in the conference room confirmed the findings. She could not determine if the discrepancies were related to data entry or if the Laboratory Information System did some type of rounding conversion.