

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0933839	(X3) Date Survey Completed 06/08/2021
Name of Provider or Supplier Valley Day And Night Clinic	Street Address, City, State 3302 Boca Chica Blvd Suite 109, 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	<p>The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of the manufacturer's instructions for Becton Dickinson (BD) vacutainer blood collection tubes, review of the laboratory's environmental monitoring records from January 1, 2021 to May 31, 2021, and staff interview, it was revealed the laboratory failed to have documentation of monitoring the temperature in the drug screening room where blood collection tubes were stored.</p>

The findings were: 1. Surveyor observation of blood collection tubes stored in the drug screening room on June 8, 2021 at 13:15 hours found 32 BD serum tubes (lot #8334796, expiration date: 11-30-2020). No means to monitor the room temperature was found. 2. A review of the manufacturer's instructions for the BD vacutainer blood collection tubes revealed the manufacturer required the tubes to be stored at a temperature range of 4 - 25C. 3. A review of the laboratory's temperature monitoring records from January 1, 2021 to May 31, 2021 revealed the laboratory failed to have documentation of monitoring the temperature in the drug screening room where tubes were stored. 4. The laboratory was asked to provide documentation of monitoring the temperatures to ensure the tubes were stored within the manufacturer's required ranges. No documentation was provided. 5 An interview with the technical consultant on 06/08/2021 at 13:20 hours in the office confirmed the findings.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on review of laboratory temperatures records from June 2020 to March 31, 2021, and confirmed in staff interview, it was revealed the laboratory failed to provide documentation of performing corrective action when room and refrigerator temperatures were documented out of the laboratory's established range or not recorded. The findings were: 1. Review of laboratory environmental and refrigerator records from June 2020 to March 31, 2021 revealed the laboratory had the following established ranges: Lab Temperature Room: 20 degrees Celsius to 25 degrees Celsius Laboratory Refrigerator Temperature: 2 degrees Celsius to 8 degrees Celsius 2. Further review of the records revealed the following dates when the temperatures were documented outside of the laboratory's established range: June 21, 2020 no documentation of monitoring room or refrigerator temperature January 7, 2021 refrigerator temperature documented at 9 degrees Celsius January 8, 2021 refrigerator temperature documented at 10 degrees Celsius January 10, 2021 refrigerator temperature documented at 9 degrees Celsius January 19, 2021 refrigerator temperature documented at 9 degrees Celsius January 25, 2021 refrigerator temperature documented at 9 degrees Celsius March 19, 2021 refrigerator temperature documented at 9 degrees Celsius 3. The laboratory was asked to provide documentation of performing corrective action when temperatures were documented out of range. No documentation was provided. 4. The findings were confirmed in an interview with the technical consultant on June 8, 2021 at 14:30 hours after her review of the records.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's personnel records, review of patient records, and confirmed in staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 15 testing personnel to perform moderate complexity testing (refer to D6065).

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the education to qualify 1 of 15 testing personnel to perform moderately complex testing. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 06/08/2021) revealed the laboratory identified 15 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the education of testing personnel number 15 (as listed on Form CMS 209). 3. The laboratory was asked to provide documentation of the educational qualifications for testing personnel number 15. No documentation was provided. 4. Random review of patient test records found testing personnel #15 (as listed on Form CMS-209) performed moderate complexity testing (CBCs) on the following dates: May 17, 2021 Specimen Accession Number: 583799 Specimen Accession Number: 583742 Specimen Accession Number: 583773 May 18, 2021 Specimen Accession Number: 584133 May 19, 2021 Specimen Accession Number: 584300 5. An interview with testing personnel number 15 (as listed on Form CMS 209) on 06/08/2021 in the office revealed she was currently working with another organization to obtain her education records. This confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services