

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0538637	(X3) Date Survey Completed 05/20/2021
Name of Provider or Supplier Valley Hospital Medical Center Laboratory	Street Address, City, State 620 Shadow Ln, Las Vegas, NV	
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	This Statement of Deficiencies was created as a result of an on-site CLIA validation survey conducted at your facility on May 20, 2021. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2019 College of American Pathologist (CAP) Proficiency Testing (PT) results, the director approved PT policy and procedure, and an interview with the Cardiopulmonary Department Director, and Point of Care Coordinator, the laboratory failed to meet the twice per year verification of accuracy requirement for the Activated Clotting Time (ACT) test. Findings include: 1. The laboratory did not achieve a passing score of 80% for the proficiency testing event CT2-B 2019. The reported result for Specimen CT2-05 was 73.0 seconds. The acceptable range was 117.8 to 295.9 seconds. The laboratory score for the event was 67%. 2. The laboratory procedure entitled "Quality Assurance, Section D, Proficiency Testing" did not establish a policy and procedure with criteria for acceptability to ensure that the laboratory verified the accuracy of the ACT test at least twice annually in the event of a proficiency testing failure. 3. The Cardiopulmonary Department Director and the Point of Care Coordinator confirmed the findings during an interview on May 20, 2021 at approximately 11:45 AM. The laboratory performs approximately 858 hematology tests annually.</p>

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory records for the comparison studies, the director approved quality assurance procedure and an interview with the Cardiopulmonary Department Director and Point of Care Coordinator, the laboratory failed to ensure that comparison studies for the ACT test was performed for all methodologies or instruments on which testing was performed, and to establish criteria for acceptability of the results of the comparison studies. Findings include: 1. The laboratory failed to perform comparison studies twice per year between the Medtronic HMS ACT instrument used in the operating room, and the Hemochron Jr. ACT instruments used in the cardiac catheterization laboratory. 2. The Policy and Procedure entitled "Quality Assurance, Section J. Equipment" did not define the criteria for acceptability for the comparison studies. The procedure stated, "Tests performed using different methodologies or instruments will be evaluated at least biannually to verify comparability of results." 3. The Cardiopulmonary Department Director and the Point of Care Coordinator confirmed the finding during an interview conducted on May 20, 2021 at approximately 11:30 AM, and via email correspondence received on May 24, 2021 received at 1:03 PM. The laboratory performs approximately 858 hematology tests annually.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on a random audit of patient tests reported between the dates of May 1, 2019 and February 12, 2021, and an interview with the Cardiopulmonary Department Director and the Point of Care Coordinator, the laboratory failed to establish a policy and procedure to ensure that the location of the laboratory where the test was performed was included on the final laboratory report. Findings include: 1. A random audit of nine patient tests performed between the dates of May 1, 2019 and February 12, 2021 revealed that the physical location where the ACT test was performed was not indicated on five of the final reports. 2. The final patient test results were entered into the Cerner Laboratory Information System (LIS) by the Valley Medical Center Laboratory personnel from the main laboratory located at 701 S. Tonopah Drive. No

written policy was established instructing the staff to enter a result comment that indicated the test was performed at the Valley Hospital Medical Center Cardiac Catheterization Laboratory. 3. The result comment present on the five reports stated the name of the main laboratory personnel who entered the result, along with a notation stating the date, time and identity of the cardiac catheterization laboratory personnel who performed the test. 4. The Cardiopulmonary Department Director and the Point of Care Coordinator confirmed the findings during an interview conducted on May 20, 2021 at approximately 12:00 PM. The laboratory performs approximately 858 hematology tests annually.