

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D1001254	(X3) Date Survey Completed 05/25/2021
Name of Provider or Supplier Er At Desert Springs An Ext Of Valley Hospital	Street Address, City, State 2075 E Flamingo Rd, 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	<p>This Statement of Deficiencies was created as a result of an on-site CLIA validation survey conducted at your facility on May 25, 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.</p>
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 College of American Pathologists (CAP) 2020 Proficiency Test (PT) results, a review of the Participant Summary for the PT event, a review of the director approved proficiency testing procedure, and an interview with the Director of the Cardiopulmonary & POCT Department, and the Supervisor of the Respiratory Therapy, the laboratory failed to meet the requirement for the twice per year verification of accuracy for the Citrated Kaolin (CK) K-Time test. Findings include: 1. A review of the 2020 Viscoelastic Studies (VES) testing event B revealed that the laboratory's CK K-time result for specimen number VES-04 was not consistent with the results of the peer group laboratories performing the test. The reported result was 2.1 minutes. The laboratory standard deviation index (SDI) was 5.4. The participant summary stated that mean of the reported results was 0.91 minutes, and the acceptable range was 0.5-1.8 minutes. There was no documentation of an investigation to determine the cause of the bias of the laboratory's reported results from those of the peer group. 2. The director approved policy and procedure titled "Point of Care Laboratory and Pulmonary - Proficiency Testing" stated "Educational Challenges that do not distinguish acceptable or unacceptable results</p>

must be reviewed in detail by the medical director using the participant summary. The medical director must note their impression of our results versus the participant summary. All bias trending results will be investigated." 3. The laboratory director reviewed the results on November 13, 2020. The laboratory director noted that the proficiency testing results were acceptable. 5. The Director of the Cardiopulmonary & POCT Department, and the Supervisor of Respiratory Therapy confirmed the findings during an interview conducted on May 25, 2021 at approximately 3:45 PM. The laboratory performs approximately 2660 hematology tests annually.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
Based on direct observation, a review of the manufacturer's instructions, a review of the laboratory's established Individual Quality Control Plan (IQCP) for the Thromboelastography (TEG) test, and an interview with the Director of the Cardio-Pulmonary and Point of Care Testing (POCT) department and Supervisor of Respiratory, the laboratory failed to ensure that the manufacturer's instructions were followed for the storage of the Platelet Mapping ADP, and the Citrated K, KH, RT, FF test cartridges. Findings include: 1. Seven of ten test cartridges for the Platelet Mapping ADP, and one of ten test cartridges for the Citrated K, KH, RT, FF tests were observed stored at ambient (room) temperature, with an acceptable room temperature range of 4.0-25.0 degrees Celsius (C) 2. The manufacturer's instructions for Platelet Mapping ADP and the Citrated K, KH, RT, FF tests stated on page 3 of the package insert that the cartridges must be protected from temperature extremes above 35 degrees C and should be stored refrigerated at 2-8 degrees C prior to use. 3. The laboratory's established IQCP for the TEG test stated in the reagents portion of the risk assessment that, "Cartridges should be kept in their sealed pouches and in the specified storage conditions (2-8 deg C) until just before use. Cartridges can be used directly from the refrigerator; they do not need to reach room temperature before use." 4. The findings were confirmed during an interview conducted on May 25, 2021 at approximately 4:30 PM with the Director of Cardio-Pulmonary and POCT, and the Supervisor of Respiratory. The laboratory performs approximately 2660 hematology tests annually.

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, a review of

the director approved quality assurance procedure and an interview with the Cardiopulmonary Department & POCT Director and the Supervisor of Respiratory Therapy, 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 I-Stat instruments used in the cardiac catheterization laboratory. 2. The policy entitled "Point of Care and Pulmonary Laboratory-LQC, EQC & Other Validations" stated under section G. Methodology Comparative Studies that for ACT, no comparative methodology exists; will compare device to device twice per year." There was no established criteria for acceptability for the comparison studies to ensure the accuracy of patient test results. 3. The Director of the Cardiopulmonary & POCT and the Supervisor of Respiratory Therapy confirmed the finding during an interview conducted on May 25, 2021 at approximately 3:00 pm, and via email correspondence received on May 28, 2021 received at 1:54 PM. The laboratory performs approximately 2660 hematology tests annually.