Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D1051228	05/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Desert Springs Hospital Pulmonary Lab	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	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.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of College of American Pathologists (CAP) Proficiency Testing (PT) results for 2019 and 2020, a review of the director approved proficiency testing policy, and an interview with the Director of the Cardiopulmonary & POCT department, and the Supervisor of Respiratory Therapy, the laboratory failed to PT review results that were ungraded or received exception codes accoding to the participant summary, and to document the findings of the review. Findings include: 1. The 2019 first testing event, AQI-A, specimen AQI-02 results for PCO2, Total CO2, Hematocrit, and Hemoglobin were not graded. The exception code for PCO2, Total CO2, and Hemoglobin indicated that the results were outside the analytical range of the I-Stat analyzer. The exception code for Hematocrit indicated that the reported result was qualified with a greater than or less than sign, so was unable to be evaluated. There was no documentation of laboratory review. 2. The 2019 third testing event, AQI-C, specimen AQI-13 results for PCO2, Total CO2, Hematocrit, and

	Hemoglobin were not graded. The exception code for PCO2, Total CO2, and Hemoglobin indicated that the results were outside the analytical range of the I-Stat analyzer. The exception code for Hematocrit indicated that the reported result was qualified with a greater than or less than sign, so was unable to be evaluated. There was no documentation of laboraory review of the ungraded results according to the participant summary to evaluate the laboratory's performance compared to the peer group to ensure the accuracy of the PT results, and to perform corrective action if required. 3. The 2020 second testing even, AQI-B, specimen AQI-07 results for PCO2, and Total CO2 were not graded. The exception code for PCO2, and Total CO2 indicated that the results were outside the analytical range of the I-Stat analyzer. There was no documentation of laboratory review of the ungraded results according to the participant summary to evaluate the laboratory's performance compared to the peer group to ensure the accuracy of the PT results, and to perform corrective action if required. 4. The policy entitled "Point of Care Laboratory and Pulmonary - Proficiency Testing" stated in section III. Policy that ,"Educational Challenges that do not distinguish acceptable or unacceptable results must be reviewed in detail by the medical director using the particpant summary. The medical director must note their impression of our results versus the participant summary." 5. The Director of the Cardiopulmonary & POCT department, and the Supervisor of Respiratory Therapy confirmed the findings during an interview conducted on May 26, 2021 at approximately 10:30 AM. The laboratory performs approximately 12,080 chemistry tests and 5080 hematology tests annually.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the 2019 CAP PT results, a revie of the director approved proficiency testing policy, and an interview with the Director of the Cardiopulmonary & POCT department, and the Supervisor of Respiratory Therapy, the laboratory failed to perform and document corrective action for unacceptable proficiency testing results. Findings include: 1. The 2019 second testing event, AQI-B, specimen AQI-06 result for PCO2 was not acceptable. The reported result was 51 mm Hg. The established limit of acceptability was 39 mm Hg to 50mm Hg. There was no documentation of an investigation for the unacceptable PT PCO2 result for specimen AQI-06. 2. The policy entitled "Point of Care Laboratory and Pulmonary - Proficiency Testing" stated in "Section IV. Procedure, Step 6" that, "If the results are not positive, a report regarding any corrective action will be filed with the appropriate committees /offices. An investigation form will be completed and reviewed/signed by the medical director." 3. 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 10:30 AM. The laboratory performs approximately 12,080 chemistry tests and 5080 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, the director approved policy, and an interview with the Director of the Cardiopulmonary & POCT department, and the Supervisor of Respiratory Therapy, the laboratory failed to ensure that comparison studies for the Arterial Blood Gas (ABG) 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 Abbott I-Stat instrument used in the operating room, and the Radiometer ABL 90 Flex Plus instruments used in the cardiopulmonary laboratory. 2. The policy entitled "Point of Care and Pulmonary Laboratory-LQC, EQC & Other Validations" stated under section "G. Methodology Comparative Studies" that for ABG w/Lytes, twice per year testing versus the main laboratory for Potassium, Sodium, HCT, Hemoglobin." The policy also stated under section "D. Arterial Blood Gas" that twice per year comparison of all devices." 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 department and the Supervisor of Respiratory Therapy confirmed the finding during an interview conducted on May 25, 2021 at approximately 11:00 AM, and via email correspondence received on May 28, 2021 received at 1:54 PM. The laboratory performs approximately 12,080 chemistry tests and 5080 hematology tests annually.