

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2062777	(X3) Date Survey Completed 04/24/2019
Name of Provider or Supplier Green Valley Fertility Partners	Street Address, City, State 2510 Wigwam Pkwy Ste 201, Henderson, 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 recertification survey conducted at your facility on April 24, 2019. 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 American Association of Bioanalysts (AAB) proficiency testing results for testing year 2017 and 2018 and an interview with the embryology supervisor, the laboratory failed to at least twice annually, verify the accuracy of non-regulated analytes performed by the laboratory. Findings include: 1. The laboratory failed to verify, at least twice annually, the traditional slide and the digital slide sperm morphology for testing year 2018 and for digital slide sperm morphology for testing year 2017. 2. The AAB proficiency testing results for the first event S2 Andrology and Embryology for testing year 2018, revealed a failing score of 50% for traditional slide and digital slide sperm morphology. There was one AAB passing proficiency testing score in 2018 for the traditional slide and digital slide sperm morphology. There was no additional verification of accuracy performed. 3. The AAB proficiency testing results for the first event S2 Andrology and Embryology for testing year 2017 revealed a failing score of 50% for digital sperm morphology. There was one AAB passing proficiency testing score in 2017 for the digital slide sperm morphology. There was no additional verification of accuracy performed. This was confirmed by the embryology supervisor on April 24, 2019 at approximately 3:00 PM. The</p>

laboratory performs approximately 2,850 Chemistry and Hematology patient tests annually.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of the personnel training and competency records for testing year 2017 and 2018 and an interview with the embryology supervisor, the laboratory director failed to ensure that prior to testing patient samples, the testing personnel have documentation of the appropriate training to perform the type and complexity of services offered by the laboratory. Findings include: A review of the personnel training and competency assessment for 2017 and 2018 revealed that the laboratory director failed to provide evidence of training for one of four testing personnel before patient laboratory testing was performed. This was confirmed by the embryology supervisor on April 24, 2019 at approximately 2:30 PM. The laboratory performs approximately 2,850 Chemistry and Hematology patient tests annually.