

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2062777	(X3) Date Survey Completed 10/27/2021
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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on October 27, 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	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>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).</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts (AAB) Proficiency Testing (PT) results for the 2020 andrology test event one and the results for the 2021 Andrology test event one, a review of the AAB Participant Statistics for the 2020 Andrology test event one and for the 2021 andrology test event one, a review of the Frequently Asked Questions (FAQ) from the AAB website, and an interview with the laboratory supervisor, the laboratory failed to verify the accuracy of the ungraded Sperm Cell Identification results for the 2020 test event one and the laboratory failed to verify the accuracy of the results for the ungraded traditional Sperm Count , and verify the results for the ungraded Sperm Cell Identification for the 2021 test event one, and to document corrective action, if required. Findings include: 1. The AAB 2020 PT Andrology Qualitative test event number one Sperm Cell Identification sample number 5 results were not graded. The laboratory reported a result of "Normal." According to the AAB report for the event, the correct result was</p>

"Abnormal head." 2. A review of the Participant Statistics for the 2020 Andrology Qualitative results revealed that for sample number 5, 89 of 247 total laboratories reported that the cell was normal. There was no documentation of a review of the Participant Statistics or corrective action. 3. The AAB 2021 PT Andrology Quantitative test event number one Traditional Sperm Count, sample number 2 were not graded. The laboratory reported a result of 27 million/ml. The acceptable range for the traditional sperm count was 11-25 million/ml. 4. A review of the participant statistics for the AAB 2021 PT Andrology Quantitative results revealed that for sample number 2, 196 laboratories reported performing the sperm count by the Makler method. The Participant Statistics did not provide a further breakdown of the number of laboratories that reported results outside the acceptable range to indicate the reason for the ungraded status of the sample. There was no documentation of a review of the Participant Statistics or corrective action. 5. The AAB website Frequently Asked Questions (FAQ) page stated that a question mark (?) on the graded report indicated that the specimen result was not graded due to lack of participant consensus. The explanation went on to state, "This score may not truly evaluate performance for the specimen which was not graded because of a lack of participant consensus. You have received a default score of 100 for this sample because our statistical checks indicated your group was not valid. You need to review this result to make sure that you can defend your response as accurate. Generally, if your result is within the given acceptable range, at a minimum a documented QA/QC review is required." The explanation further stated, "If you are outside the given acceptable range, you either need to justify why this range is not appropriate, or treat this as a miss requiring corrective action." 6. The AAB 2021 PT Andrology Qualitative test event one for the Sperm Cell Identification, sample one was not graded due to lack of participant consensus. The laboratory reported a result of "Abnormal head." The acceptable result according to the proficiency testing report was "Normal." There was no documentation of a review of the Participant Statistics or corrective action. 7. A review of the Participant Statistics for the 2021 Andrology Qualitative test event one Sperm Cell Identification for sample one revealed that 107 of 296 total laboratories reported the result of "Abnormal head." 8. The laboratory supervisor confirmed that there had been no review of the Participant Statistics for the ungraded results during an interview conducted on October 27, 2021 at approximately 11:45 AM. The laboratory performs approximately 2000 endocrinology tests and 1800 hematology tests annually.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:

Based on a review of the American Association of Bioanalysts (AAB) Proficiency Testing (PT) reports for the 2019 Andrology test event two, a review of the PT report for the 2020 Andrology test events one and two, a review of the director approved policy entitled, "Proficiency Testing Policy," and an interview with the laboratory supervisor, the laboratory failed to verify the accuracy of the Sperm Morphology test, and the Sperm Count test twice annually. Findings include: 1. The laboratory failed to verify the accuracy of the traditional and digital Sperm Morphology tests, and the digital slide Sperm Morphology tests during the years of 2019 and 2020. 2. The laboratory received a score of zero for the AAB 2019 the Andrology Quantitative PT

test event two digital slide Sperm Morphology result. For specimen number 6, the laboratory reported a result of 12% normal, which was outside the acceptable range of 0-11% normal. For specimen number 7, the laboratory reported a result of 16% normal, which was outside the acceptable range of 0-14% normal. 3. The laboratory received a score of 50% for the AAB 2020 Andrology Quantitative PT test event one video Sperm Count result. For specimen 2, the laboratory reported a result of 46 million/ml, which was outside the acceptable range of 16-30 million/ml. 4. The laboratory received a score of 50% for the AAB 2020 Andrology Quantitative PT test event two traditional slide Sperm Morphology result. For specimen 7, the laboratory reported 15% normal, which was outside the acceptable range of 0-14% normal. 5. The laboratory received a score of zero for the AAB 2020 the Andrology Quantitative test event two digital slide Sperm Morphology result. For specimen 6, the laboratory reported 17% normal, which was outside the acceptable range of 1-15% normal. For specimen 7, the laboratory reported 15% normal, which was outside the acceptable range of 0-13% normal. 6. The director approved policy entitled, "Proficiency Testing Policy," section L, entitled, "Corrective Action for Failures in Twice Annually Testing Events" stated, "In the Case (sic) of a failure of a test that the external Proficiency Testing vendor provides twice annually, it is necessary to successfully pass a third testing event. In such cases, past proficiency material will be used, and each technologist performing the test in house must perform the tests, and the results will be reviewed and must per (sic) within the acceptable range of the original proficiency test results data." 7. The laboratory supervisor confirmed the finding during an interview conducted on October 27, 2021 at approximately 11:45 AM. The laboratory performs approximately 2000 endocrinology tests and 1800 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 American Association of Bioanalysts (AAB) Proficiency Testing (PT) reports for the 2019 Andrology test event two, a review of the PT report for the 2020 Andrology test events one and two, a review of the director approved policy and procedure for the proficiency testing, and an interview with the laboratory supervisor, the laboratory failed to document corrective actions for the proficiency testing results which received unacceptable scores for the Sperm Morphology test, the Sperm Count test, and the Sperm Cell identification tests. Findings include: 1. The laboratory received a score of zero for the AAB 2019 Andrology Quantitative test event two digital slide Sperm Morphology result with no documentation of corrective action. For specimen number 6, the laboratory reported a result of 12% normal, which was outside the acceptable range of 0-11% normal. For specimen number 7, the laboratory reported a result of 16% normal, which was outside the acceptable range of 0-14% normal. 2. The laboratory received a score of 50% for the AAB 2020 Andrology Quantitative test event one video Sperm Count result with no documentation of corrective action. For specimen 2, the laboratory reported a result of 46 million/ml, which was outside the acceptable range of 16-30 million/ml. 3. The laboratory received a score of 80% for the AAB 2020 Andrology Qualitative test event one Sperm Cell Identification results with no documentation of corrective action for the incorrect result. For specimen 1, the laboratory reported the cell identification as "Abnormal mid-piece." The acceptable result was "Normal." 4. The laboratory

received a score of 50% for the AAB 2020 Andrology Quantitative test event two traditional slide Sperm Morphology result with no documentation of corrective action. For specimen 7, the laboratory reported a result of 15% normal, which was outside the acceptable result of 0-14% normal. 5. The laboratory received a score of zero for the 2020 Andrology Quantitative test event two digital slide Sperm Morphology result with no documentation of corrective action. For specimen 6, the laboratory reported a result of 17% normal, which was outside the acceptable range of 1-15% normal. For specimen 7, the laboratory reported a result of 15% normal, which was outside the acceptable range of 0-13% normal. 6. The director approved policy and procedure entitled, "Proficiency Testing Policy" stated in step 5, "Unacceptable results will be investigated and corrective action taken," and step 6, "The corrective action will be documented in detail, and attached to the PT results computer printout." 7. The laboratory supervisor confirmed the findings during an interview conducted on October 27, 2021 at approximately 2:45 PM. The laboratory performs approximately 2000 endocrinology tests and 1800 hematology tests annually.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on a review of the Tosoh AIA-360 maintenance records for 2019, 2020, and 2021, a review of the Tosoh AIA-360 Operator's Manual, Chapter 10 entitled, "Daily Maintenance Procedures," and an interview with the laboratory supervisor, the laboratory failed to ensure that the six month maintenance was performed and documented. Findings include: 1. There was no documentation of the six month maintenance for the Tosoh AIA-360 analyzer between the months of April 2019 and September 2021. 2. The operator's manual for the Tosoh AIA-360 stated in Chapter 10 entitled, "Daily Maintenance Procedures," Section 5 entitled, "Six-Month Cycle Maintenance Procedures" to perform cleaning of the diluent and wash lines, and to replace the filters for the diluent and wash solution bottles. 3. The laboratory supervisor confirmed the finding during an interview conducted on October 27, 2021 at approximately 1:30 PM. The laboratory performs approximately 2000 endocrinology tests and 1800 hematology tests annually.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory estradiol quality control records, a review of the

manufacturer's instructions for the Biorad Liquichek Immunoassay Plus Control, a review of the director approved policy entitled, "Nonconformance and Corrective Action Policy," and an interview with the laboratory supervisor, the laboratory failed to perform and document corrective action for the unacceptable quality control results for the level 1 quality control solution on three of 21 days in December, 2020. Findings include: 1. The level 1 quality control solution for the estradiol test was outside the acceptable range with no documentation of corrective action on the dates of December 21, 2020, December 22, 2020, and December 23, 2020. The acceptable range established by the manufacturer of the Biorad Liquichek Immunoassay Plus Control, lot number 85231 was 138-256 pg/ml. On December 21, 2020, the control result was documented as 283.1 pg/ml. On December 22, 2020, the control result was documented as 269.8 pg/ml. On December 23, 2020, the control result was documented as 283.8 pg/ml. On each day, a comment written on the log stated, "2/3 in #1 high out." No further corrective action was recorded. 2. The director approved policy entitled, "Nonconformance and Corrective Action Policy," in the section entitled "Course of Action for an Out-of-Control Event" stated that if the QC fails, the steps to follow were to troubleshoot the analyzer and reagent. It went on to state to be sure the controls are well mixed, and to repeat the quality control with fresh control solution, and if still not resolved, the next step stated to recalibrate and rerun the QC. Finally, if the problem is still not resolved, the policy states to contact technical support, and to send out patient samples to a reference laboratory. 3. The laboratory supervisor confirmed the findings during an interview conducted on October 27, 2021 at approximately 2:00 PM. The laboratory performs approximately 2000 endocrinology tests and 1800 hematology tests annually.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on a review of the American Association of Bioanalysts (AAB) Andrology qualitative and quantitative Proficiency Testing (PT) results of Sperm Count, Sperm Morphology, and Sperm Cell Identification tests for 2019, 2020, and 2021, a review of the 2019, 2020, and 2021 laboratory quality control records for the Tosoh AIA-360 estradiol and hCG tests, a review of the Tosoh AIA-360 maintenance logs for 2019, 2020, and 2021, a review of the director approved laboratory policy entitled "Proficiency Testing," a review of the director approved laboratory policy entitled, "Nonconformance and Corrective Action Policy," and a review of the Tosoh AIA-360 operator's manual Chapter 10, entitled, "Daily Maintenance Procedures," the director failed to ensure that the established quality assessment program was maintained to detect and correct failures in quality when they occurred. Findings include: 1. A review of the AAB PT results for 2019, 2020, and 2021 revealed that there was no documentation of corrective action for the proficiency testing failures for the 2019 event 2 quantitative digital slide Sperm Morphology result, the 2020 event one video Sperm Count result, the 2020 event two traditional slide and digital slide quantitative Sperm Morphology results, and no documentation of a review of the ungraded 2020 event one qualitative Sperm Cell identification sample 5, the ungraded 2021 event one traditional Sperm Count sample 2, and the 2021 event one qualitative Sperm Cell identification sample 1, as required in the director approved policy entitled

"Proficiency Testing." 2. A review of the laboratory estradiol quality control records for December 2020 revealed that the level 1 quality control result was outside the established acceptable range with no documentation of corrective action on three consecutive days in December, 2021. The laboratory approved policy entitled, "Nonconformance and Corrective action" specified corrective action steps to take in the event that the quality control results were unacceptable. 3. A review of the Tosoh AIA-360 maintenance logs for 2019, 2020, and 2021 revealed that the 6-month maintenance was not performed and documented in accordance with the manufacturer's instructions outlined in Chapter 10 of the Tosoh AIA-360 operator's manual entitled, "Daily Maintenance Procedures." 4. A review of the 2019, 2020, and 2021 AAB PT reports, the monthly quality control records for the Tosoh AIA-360, and the monthly maintenance logs revealed that the AAB Andrology PT results for 2019, 2020, and 2021, the for the Tosoh AIA-360 estradiol quality control results for December 2020, and the Tosoh AIA-360 maintenance logs for 2019, 2020, and 2021 were reviewed and approved by the laboratory director with no documentation of corrective actions. The laboratory performs approximately 2000 endocrinology tests and 1800 hematology tests annually.