

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2202955	<b>(X3) Date Survey Completed</b> 11/12/2021
<b>Name of Provider or Supplier</b> Give Legacy - Texas, Llc	<b>Street Address, City, State</b> 21708 Hardy Oak Blvd # 104, San Antonio, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was found to be out of compliance based on the following <b>CONDITION LEVEL DEFICIENCY: D5024 - 42 C.F.R. 493.1415 Condition: Hematology</b> Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
<b>D5024</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This <b>CONDITION</b> is not met as evidenced by: Based on review of the laboratory's records, review of the laboratory's test systems, and staff interview, it was revealed the laboratory failed to meet the requirements for the specialty of hematology. The findings include: 1. The laboratory failed to have documentation of pre-analytic studies for non- FDA approved tests (refer to D5311). 2. The laboratory failed to have documentation of establishment studies for semen analysis and DNA fragmentation testing performed (refer to D5423). 3. The laboratory failed to have documentation of performing quality control testing each day</p>

of patient testing (refer to D5447). 4. The laboratory failed to have documentation of monitoring quality control values over time to detect shifts and trends (refer to D5469).

**D5311**

**SPECIMEN SUBMISSION, HANDLING, AND REFERRAL**  
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's test menu, and staff interview, it was revealed the laboratory failed to have documentation of establishing pre-analytical requirements for two non-FDA approved tests. The findings include: 1. A review of the laboratory's test menu revealed the laboratory utilized the following two non-FDA approved tests: a) Hamilton Thorne Ceros II semen analysis, and b) Halotech Halosperm G2 DNA fragmentation. 2. The laboratory was asked to provide documentation of establishing the required pre-analytic requirements for the assays. No documentation was provided. 3. The laboratory performed 15000 semen analysis tests (sperm count, sperm motility, sperm morphology) annually and 1500 DNA fragmentation tests annually. 4. An interview with the technical supervisor on 11/12/2021 at 1130 hours in his office revealed the facility did not perform any pre-analytic studies for the non-FDA approved tests. This confirmed the findings.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's test menu, and staff interview, it was revealed the laboratory failed to have documentation of performing establishment studies for two non-FDA approved tests. The findings include: 1. A review of the laboratory's test menu revealed the laboratory utilized the following two non-FDA approved tests: a) Hamilton Thorne Ceros II semen analysis, and b) Halotech Halosperm G2 DNA fragmentation. 2. The laboratory was asked to provide documentation of performing establishment studies for the assays to include: pre-analytic studies (sample storage, stability) accuracy precision, sensitivity specificity interfering substances. No

documentation was provided. 3. The laboratory performed 15000 semen analysis tests (sperm count, sperm motility, sperm morphology) annually and 1500 DNA fragmentation tests annually. 4. An interview with the technical supervisor on 11/12/2021 at 1430 hours in his office revealed the laboratory did not perform establishment studies for the non-FDA approved tests. This confirmed the findings.

**D5447**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's test menu, review of the laboratory's quality control records, and staff interview, it was revealed the laboratory failed to have documentation of performing quality control testing each day of patient testing for sperm motility and morphology. The findings include: 1. A review of the laboratory's test menu revealed the laboratory performed sperm motility and morphology utilizing the Hamilton Thorne Ceros II semen analysis system. 2. A review of the laboratory's quality control records revealed the laboratory failed to have documentation of performing quality control testing for sperm motility and morphology. The laboratory was asked to provide documentation of performing quality control testing as required. No documentation was provided. 3. The laboratory performed 5000 sperm motility and morphology tests each annually. 4. An interview with the technical supervisor on 11/12/2021 at 1130 hours in his office revealed the facility did not perform quality control testing for sperm motility or sperm morphology. This confirmed the findings.

**D5469**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's test menu, review of the laboratory's quality control records, and staff interview, it was revealed the laboratory failed to have documentation monitoring quality control values for sperm count over time. The findings include: 1. A review of the laboratory's test menu revealed the laboratory

performed sperm count, motility and morphology utilizing the Hamilton Thorne Ceros II semen analysis system. 2. The laboratory performed quality control testing for sperm count each day of patient testing. 3. The laboratory was asked to provide documentation of assessing quality control values for sperm count over time to detect shifts and trends. No documentation was provided. 3. The laboratory performed 5000 sperm counts annually. 4. An interview with the technical supervisor on 11/12/2021 at 1400 hours in his office revealed the facility did not monitor quality control values over time. This confirmed the findings.

**D6095**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's test menu, and staff interview, it was revealed the laboratory director failed to ensure acceptable levels of analytical performance were established for two non-FDA approved test systems (refer to D5423).

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(12)

The laboratory director must 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 review of the laboratory's test menu, review of the laboratory's submitted Form CMS 209, and staff interview, it was revealed the laboratory director failed to ensure testing personnel had documentation of training for two non-FDA approved tests. The findings include: 1. A review of the laboratory's test menu revealed the laboratory utilized the following two non-FDA approved tests: a) Hamilton Thorne Ceros II semen analysis, and b) Halotech Halosperm G2 DNA fragmentation. 2. A review of the laboratory's submitted Form CMS 209 revealed the facility identified 3 testing personnel. 3. The laboratory was asked to provide documentation of training for the personnel for each of the identified test systems. No documentation was provided. 3. The laboratory performed 15000 semen analysis tests (sperm count, sperm motility, sperm morphology) annually and 1500 DNA fragmentation tests annually. 4. An interview with the technical supervisor on 11/12/2021 at 1300 hours in his office revealed the facility did not have documentation of training. This confirmed the findings.