

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2285605	(X3) Date Survey Completed 04/08/2025
Name of Provider or Supplier Give Legacy - New Jersey, Llc	Street Address, City, State 22 Hudson Place, 4th Floor, Hoboken, NJ	
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
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 surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to verify the accuracy of Andrology & Embryology test results obtained from the American Association of Bioanalysts (AAB) for the S2 2024 event. The findings include: 1. The laboratory received an artificial 100% for Sperm Morphology: Cell ID. 2. Samples 7 and 10 were coded "?" "This score may not truly evaluate performance for this specimen which was not graded because of a lack of participant consensus". 3. The laboratory reported sample 7 as "normal" the PT provider reported the Mean/Intended result as "Abnormal head". 4. The laboratory reported sample 10 as "Abnormal head" the PT provider reported the Mean/Intended result as "Normal". 5. The laboratory failed 2 out of 5 PT challenges for Sperm Morphology: Cell ID event S2 2024 with a score of 60% 6. There was no documented evidence of corrective action for the above mentioned event and challenge. 7. The GS confirmed on 4/9/25 at 11:20 am accuracy of Sperm Morphology: Cell ID was not verified</p>
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>(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</p>

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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Performance Specification (PS) records Standard Operating Procedures (SOP) and interview with the General Supervisor (GS), the laboratory failed to ensure that all PS procedures were adequate for the Hamilton Thorne IVOS analyzers and DNA Fragmentation tests before being put into use from August 2023 to 4/8/25. The findings include: 1. The SOP for the rejection of samples received in Transport Media (TM) stated "VI. The sample has been in transit for more than 48 hours" it will be rejected. 2. The laboratory PS stability study for samples received in TM did not exceed 24 hours. 3. The GS confirmed on 4/8/25 at 12:00 pm that PS stability study for samples received in TM did not exceed 24 hours.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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.

This STANDARD is not met as evidenced by:

Based on the lack of Quality Control Verification (QCV) records and interview with the General Supervisor (GS), the laboratory failed to verify QC-beads Lot # 240403181 18 M/ml and lot # 241405351 35 M/ml before use for Semen Analysis (SA) tests run on the Hamilton Thorne IVOS analyzers from 9/12/24 to 4/8/25. The GS confirmed 4/8/25 at 11:15 am that QC material was not verified before putting in use.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual and interview with General

Supervisor (GS) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from August 2023 to 4/8/25. The finding includes: 1. The laboratory failed to have a procedure to verify new lots of controls before they were put in use on the Hamilton Thorne IVOS analyzers. 2. The GS confirmed on 4/8/25 at 11:40 am that the laboratory failed to have a procedure to verify new lots of controls before they were put in use.

D5805

TEST REPORT
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Test Reports (TR) for DNA fragmentation tests and interview with the General Supervisor (GS) the laboratory failed to ensure the TR included all the required information from August 2023 to 4/8/25. The findings include: 1. TR did not include the required statement for tests that have not been FDA-cleared or approved. 2. The GS confirmed on 4/8/25 at 12:00 pm, the laboratory failed to ensure the TR included all the required information.