Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0415981	(X3) Date Survey Completed 10/29/2025
Name of Provider or Supplier Duly Health And Care - Glen Ellyn Lab	**Street Address, City, State** 430 Pennsylvania Ave, Glen Ellyn, IL	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory's policy and procedure manual and interview with the technical supervisor (TS); the laboratory failed to outline all components of a test procedure for post-vasectomy semen analysis. Findings Include: 1. Review of the laboratory policy and procedure manual identified the policy, "HEME.06: Postvasectomy Semen Analysis" which failed to include quality control for post

	vasectomy semen analysis. 2. During survey date 10-29-2025, at 10:23 am, interview with TS confirmed the laboratory failed to have quality control procedures for post-vasectomy semen analysis.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, review of patient testing records, review of laboratory test volume worksheet and interview with the technical supervisor (TS); the laboratory failed to establish quality control procedures to monitor quality performance of post-vasectomy semen analysis for 118 of 118 patients tested in 2024 and 2025. Findings include: 1. Review of five of five laboratory patient testing records tilted "Post Vasectomy semen Analysis" revealed the laboratory failed to document quality control for post vasectomy semen analysis testing. 2. Review of the laboratory policy and procedure manual identified the policy, "HEME.06: Postvasectomy Semen Analysis" revealed that the laboratory failed to have a quality control process for post vasectomy semen analysis. See D5403. 3. Review of laboratory document titled "Non-waived CLIA test volumes worksheet" revealed that the laboratory performed 118 post vasectomy semen analysis tests from September of 2024 to August of 2025. 4. During survey date 10-29-2025, at 10:23 AM interview with TS confirmed the laboratory failed to have an established quality control process for post vasectomy semen analysis.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records, lack of academic records, the CMS-209 (Laboratory Personnel Report), and interview with the technical supervisor (TS); the laboratory failed to have qualifying academic records for 1 of 21 testing personnel (TP) listed on the CMS-209. See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor

	of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records, lack of academic records, the CMS-209 (Laboratory Personnel Report), and interview with the technical supervisor (TS); the laboratory failed to have qualifying academic records for 1 of 21 testing personnel (TP) listed on the CMS-209. Findings include: 1. Review of laboratory personnel records found the laboratory lacked foreign equivalency education documents to qualify TP #18 listed on the CMS-209 form, dated 10/27/2025. 2. Interview with TS on 10/28/2025 at 02:20 pm confirmed the laboratory failed to have the required qualifying academic records for TP # 18 at the time of survey.