Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2210497	01/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Positive Steps Fertility Shreveport	9391 Ellerby Road, Suite C, Shreveport, LA	

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	A Recertification Survey was conducted January 14, 2025 at Positive Steps Fertility Shreveport - CLIA ID # 19D2210497. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure, quality control records, patient test reports, and interview with personnel, the laboratory failed to perform and document quality control (QC) every eight (8) hours of patient testing for manual sperm counts. Findings: 1. Review of the laboratory's policy for "Quality Control" revealed "Perform Andrology QC using QC beads. All techs should perform QC if they perform a semen analysis. At least one level of QC beads must be performed and logged for every 8 hours worked". 2. Review of the laboratory's quality control (QC) and patient test records reviewed from January 2024 through December 2024 revealed the laboratory did not perform or document at least one level of QC for the following five (5) of five (5) patients reviewed: a) Patient 20403: Reported August 14, 2024 at 08:00 am (no QC documented) b) Patient 20027: Reported August 15, 202 at 09:00 am (no QC documented) c) Patient 20712: Reported August 15, 2024 at 13:30 pm (no QC documented) d) Patient 19723: Reported August 15, 2024 at 14:30 pm (no QC documented) e) Patient 20735: Reported August 16, 2024 at 13:30 pm (no QC documented) 3. In interview on January 14, 2025 at 1:10 pm, the Laboratory Director confirmed the testing personnel did not document the QC for the identified patients.
D5785	CORRECTIVE ACTIONS

	CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory temperature records and interview with personnel, the laboratory failed to document corrective actions performed when the room temperature was not maintained within the acceptable range per laboratory policy for six (6) of three hundred sixty six (366) days reviewed in 2024. Findings: 1. Review of the laboratory's room temperature logs for 2024 revealed the acceptable range for the room temperature as 24 degrees celsius +/= 4 degrees celsius (20 - 28 degree celsius). 2. Further review of the laboratory's room temperature logs for 2024 revealed the room temperature was documented as outside the acceptable limits without documented corrective actions for the following six (6) of three hundred sixty six (366) days reviewed: a) January 15, 2024: documented room temperature of 18 degree celsius (acceptable range of 20-28 degree celsius) b) January 16, 2024: documented room temperature of 18 degree celsius (acceptable range of 20-28 degree celsius) c) January 17, 2024: documented room temperature of 18 degree celsius (acceptable range of 20-28 degree celsius) d) April 3, 2024: documented room temperature of 18 degree celsius (acceptable range of 20-28 degree celsius) e) July 18, 2024: documented room temperature of 19 degree celsius (acceptable range of 20-28 degree celsius) f) July 23, 2024: documented room temperature of 19 degree celsius (acceptable range of 20-28 degree celsius) 3. In interview on January 14, 2025 at 11: 10 pm, the Laboratory Director confirmed the laboratory did not document corrective actions for unacceptable room temperatures for the identified dates.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; This STANDARD is not met as evidenced by: Based on review of laboratory temperature records and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policy occurred. Refer to D5785.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 review of laboratory policy, quality control and patient records, and interview with personnel, the Laboratory Director failed to ensure that a quality

	control program was maintained to assure the quality of laboratory testing. Refer to D5543.