Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 19D2210497	**(X3) Date Survey Completed** 07/16/2021
Name of Provider or Supplier Positive Steps Fertility Shreveport	**Street Address, City, State** 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	An Initial Survey was performed on July 21, 2021 at Positive Steps Fertility Shreveport, CLIA ID # 19D2210497. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's personnel records, policy and procedure manual and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the Clinical Consultant, Technical Consultant, Technical Supervisor, and General Supervisor were complete. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have written, detailed policies to assess competency for the duties assigned to the positions of Clinical Consultant, Technical Consultant, Technical Supervisor, and General Supervisor and the frequency at which the assessments will be performed if needed. 2. Review of the laboratory's personnel records revealed Personnel 1 serves as the Laboratory Director, Technical Consultant, Technical Supervisor, and General Supervisor; however, Personnel 3 serves as the Clinical Consultant. 3. Further review of the Clinical Consultant's personnel records revealed a competency assessment for the duties of Clinical Consultant was not performed. 4. In interview on July 16, 2021 at 10:30 am, the Laboratory Director stated that she is serving as all of the positions except for the Clinical Consultant and was unaware that the above policies were needed. II. Based on review of the laboratory's policy and procedure manual, personnel records and interview with personnel, the laboratory failed to ensure

	written, detailed policies and procedures to assess competency for Testing Personnel were complete. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. Further review of the laboratory's policy and procedure manual revealed how testing personnel competency will be assessed was not included as well as the frequency that the assessments will be performed. 3. Review of the laboratory's personnel records revealed the Laboratory Director did perform an initial competency assessment for Personnel 2 in April of 2021. 4. In interview on July 16, at 10:30 am, the Laboratory Director confirmed the laboratory's policy did not include the frequency and required procedures to assess competency for Testing Personnel.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish a written procedure for all aspects of testing. Findings: 1. Review of the policy and procedure manual revealed the laboratory did not have written, detailed instructions for the following: a) Proficiency Testing, to include but not all inclusive of how to test proficiency samples, who is responsible for proficiency testing reviews, and the assessment of unacceptable results, and how often proficiency testing samples are tested. b) Corrective actions to be taken when refrigerator and freezers temperatures are not within acceptable range c) Labeling of Quality Control and staining materials after being put into use for patient testing as well as the reagents and supplies also being used for patient testing. 2. In interview on July 16, 2021 at 11:00 am, the Laboratory Director confirmed the above policies were not included in the laboratory policy and procedure manual.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel. Refer to D5401.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency. Findings: 1. The laboratory failed to ensure written policies and procedures to assess competency for the Clinical Consultant, Technical Consultant, Technical Supervisor, and General Supervisor were complete. Refer to D5209 I. 2. The laboratory failed to ensure written, detailed policies and procedures to assess competency for Testing Personnel were complete. Refer to D5209 II.