

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2283100	(X3) Date Survey Completed 11/18/2025
Name of Provider or Supplier Parkview Southwest Outpatient Center	Street Address, City, State 8202 Glencarin Blvd, Fort Wayne, IN	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, record review, and interview, the laboratory failed to follow their policy to perform and document twice annual alternative Proficiency Test assessment for post vasectomy motility in conjunction with Post Vasectomy (PV) survey from College of American Pathologists (CAP) for one (2025) of two years reviewed. Findings include: 1. Review of policy (Stat ID: 15396496) titled "Proficiency Testing" last revised on 04/2024, under III. Procedure states, "1. The Laboratory will subscribe to an approved proficiency testing program for each analyte unless an alternative validation method is approved by the Technical Supervisor." 2. Review of the document "Alternative Assessment Post Vasectomy Motility Resulting" revised 03/2024, reads "The CAP survey post vasectomy presence/absence (PV survey) does not have a motility component ... Laboratories policy is to report motility if sperm are present. A report comment is added to the result line that indicates Motile or Non-motile. An alternative assessment is required for this component of reporting. This will be performed twice annually in conjunctions with the PV survey from CAP." 3. Review of document titled, "College of American Pathologist Alternative Performance Assessment (APA) Test List" revised on 03-2024, indicates the test sperm motility the assessment is performed in the months of April and October. 4. Upon request for Alternative Assessment for Post Vasectomy Motility on 11-18-2025 at 10:55 am, SP-01 (Laboratory Manager) stated the laboratory did not perform sperm motility in 2025 and this test was last assessed on 11-02-24. 5. Patient (pt) record review indicated the following patients had semen</p>

screen-post vasectomy testing performed during 2025 without alternate performance assessment reported. Patient Date Semen Screen results PT#1 2-14-2025 non-motile sperm PT#2 3-07-2025 non-motile sperm PT#3 4-08-2025 non-motile sperm PT#4 4-17-2025 non-motile sperm 6. Annual test volume for sperm motility is 37.