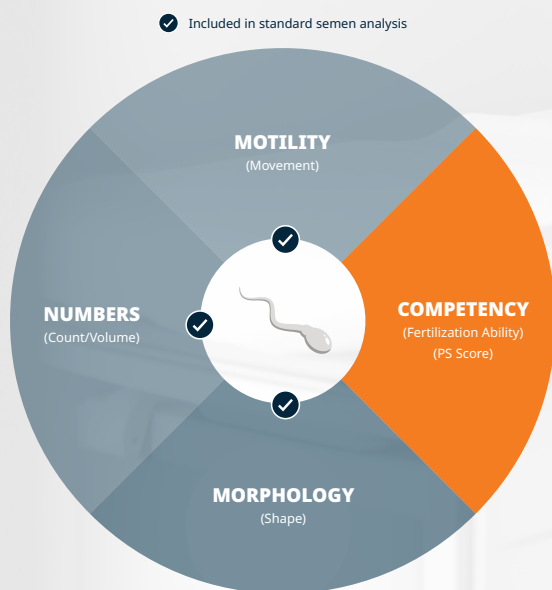


# PS Detect™ and the PS Score

## A FUNCTIONAL ASSESSMENT OF SPERM COMPETENCE

Research suggests that 20–30% of men with normal semen parameters are still infertile. PS Detect™ was developed to address this diagnostic gap by measuring sperm competence as a root cause male infertility factor.



### THE RESEARCH

Phosphatidylserine (PS) is a phospholipid that has been shown to play a functional role in fertilization. In one study, approximately 30% of patients had a normal semen analysis but a low PS Score—meaning they were misdiagnosed as fertile. Further research published in Nature Communications; JU Open Plus, 2024 has shown:

- PS expression is significantly higher in pregnancy-proven donors compared to men with infertility.
- A significant subset of men with normal semen analysis parameters demonstrate reduced PS Scores.
- PS Score can be improved to pregnancy-proven levels following varicocele repair.

### ASSOCIATION WITH VARICOCELE

Varicocele is present in up to 40% of males with infertility. In clinical data:

- Patients with varicocele demonstrated significantly lower PS Scores compared to pregnancy-proven donors.
- Following varicocele repair, PS Scores improved to levels comparable to fertile controls.
- In one cohort, >25% of couples achieved natural pregnancy after repair (data on file).
- PS Detect™ may assist in identifying patients who could benefit from further evaluation by a reproductive urologist.

**PS DETECT** 

READ THE RESEARCH AND  
LEARN MORE AT [PSFERTILITY.COM](https://psfertility.com)

Disclaimer: The PS Detect Test is a clinical semen analysis. There are many additional factors that impact fertility that the PS Detect test does not measure. The PS Detect test does not provide a comprehensive evaluation of a male's fertility status. For a comprehensive assessment of male fertility status, the patient should consult a healthcare provider. One test cannot guarantee whether or not an individual will be able to conceive a child.

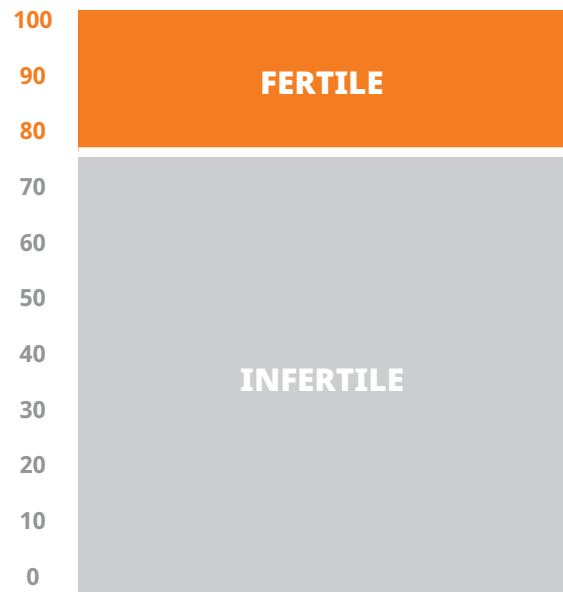
# Understanding PS Score Thresholds for Fertility Assessment

A PS Score **below 78%** reflects a **decreased ability of sperm to fertilize an egg**, and therefore, suggests infertility.

The PS Score is meant to be used in combination with a patient's history, semen analysis and physician exam to diagnose infertility and assess treatment options for fertility.

## UNDERSTANDING THE REFERENCE RANGE AND DECISION BOUNDARY

A reference range, as defined by CLSI\*, typically encompasses 95% of results from a healthy population. It is important to note that these ranges are often based solely on healthy individuals, without considering a diseased or abnormal population. For the PS Score, the 95% reference range, based exclusively on fertile males, is 64%.



To establish a more clinically relevant decision boundary between fertile and infertile patient samples, PS Fertility identified a cutoff point that optimizes sensitivity and specificity by incorporating data from both fertile and infertile samples. As a result, the sensitivity of PS Score in accurately identifying infertile men is improved.

Based on this analysis, a PS Score below 78% reflects a decreased ability of sperm to fertilize an egg, and indicates a reduced fertility capability.

*\*Clinical and Laboratory Standards Institute*

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