

Objective

To use a home test kit (SwimCount) as a home screening device or sperm quality test for measuring male fertility. This test works by measuring the sperm cells' ability to swim.

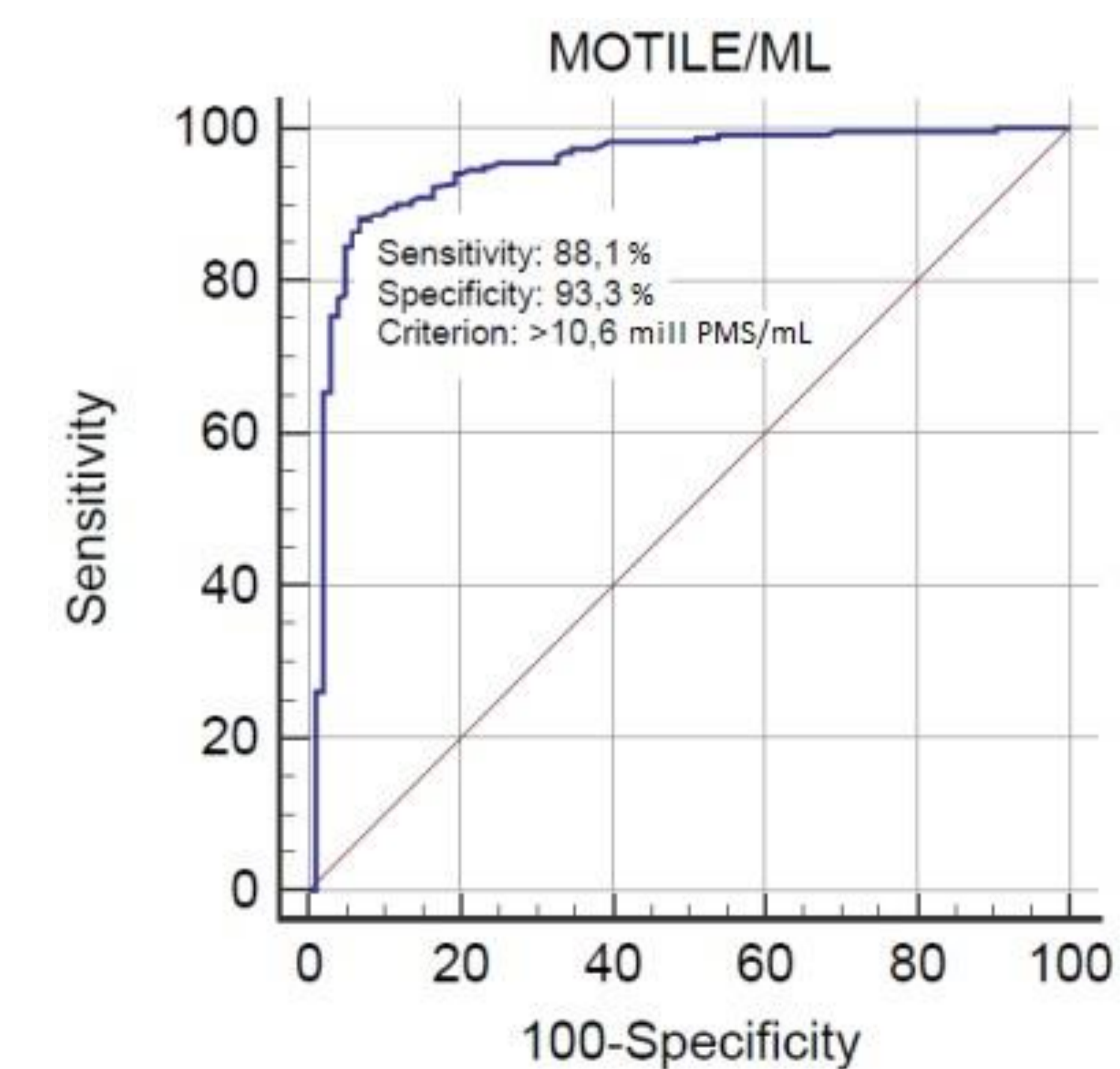
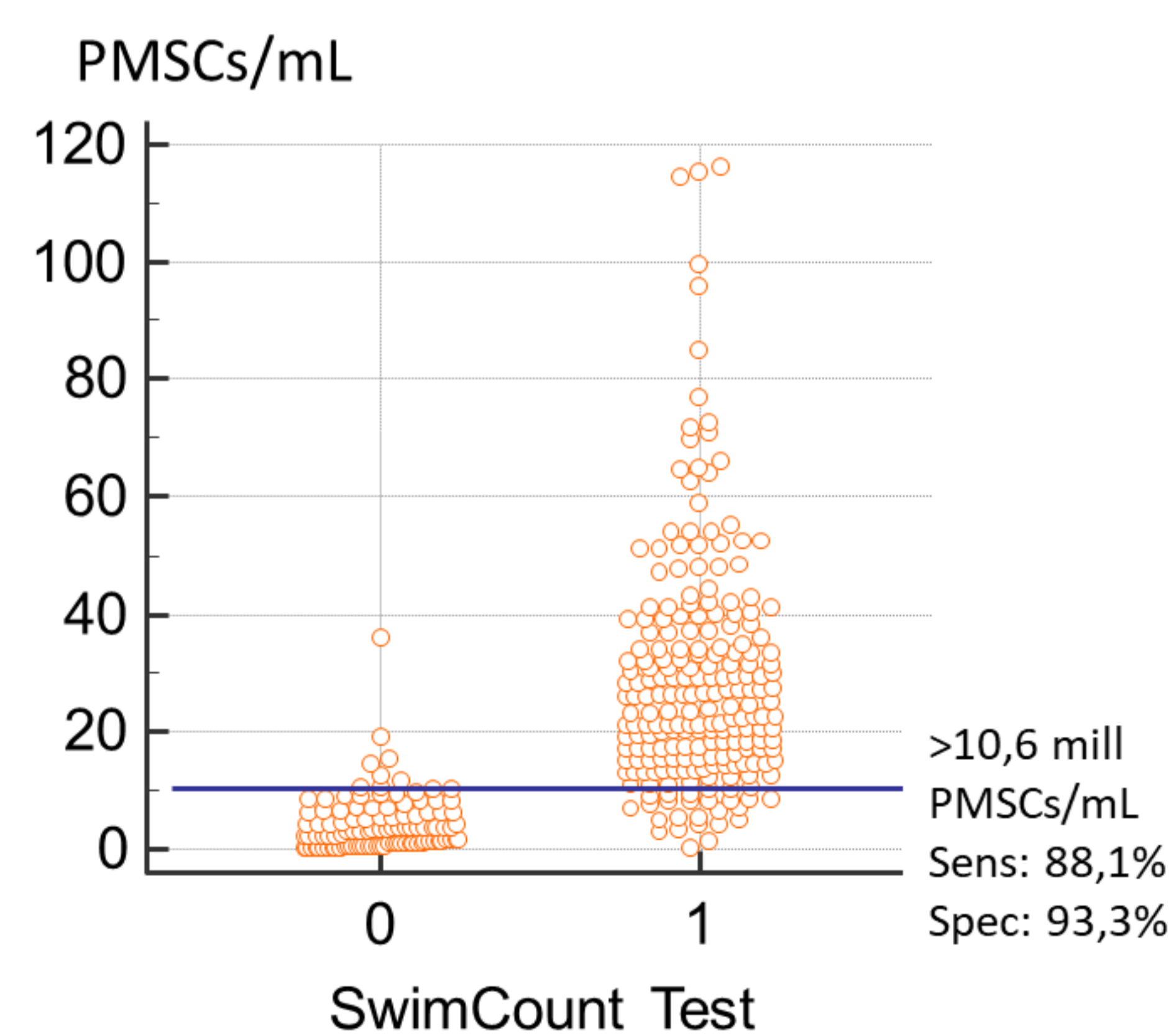
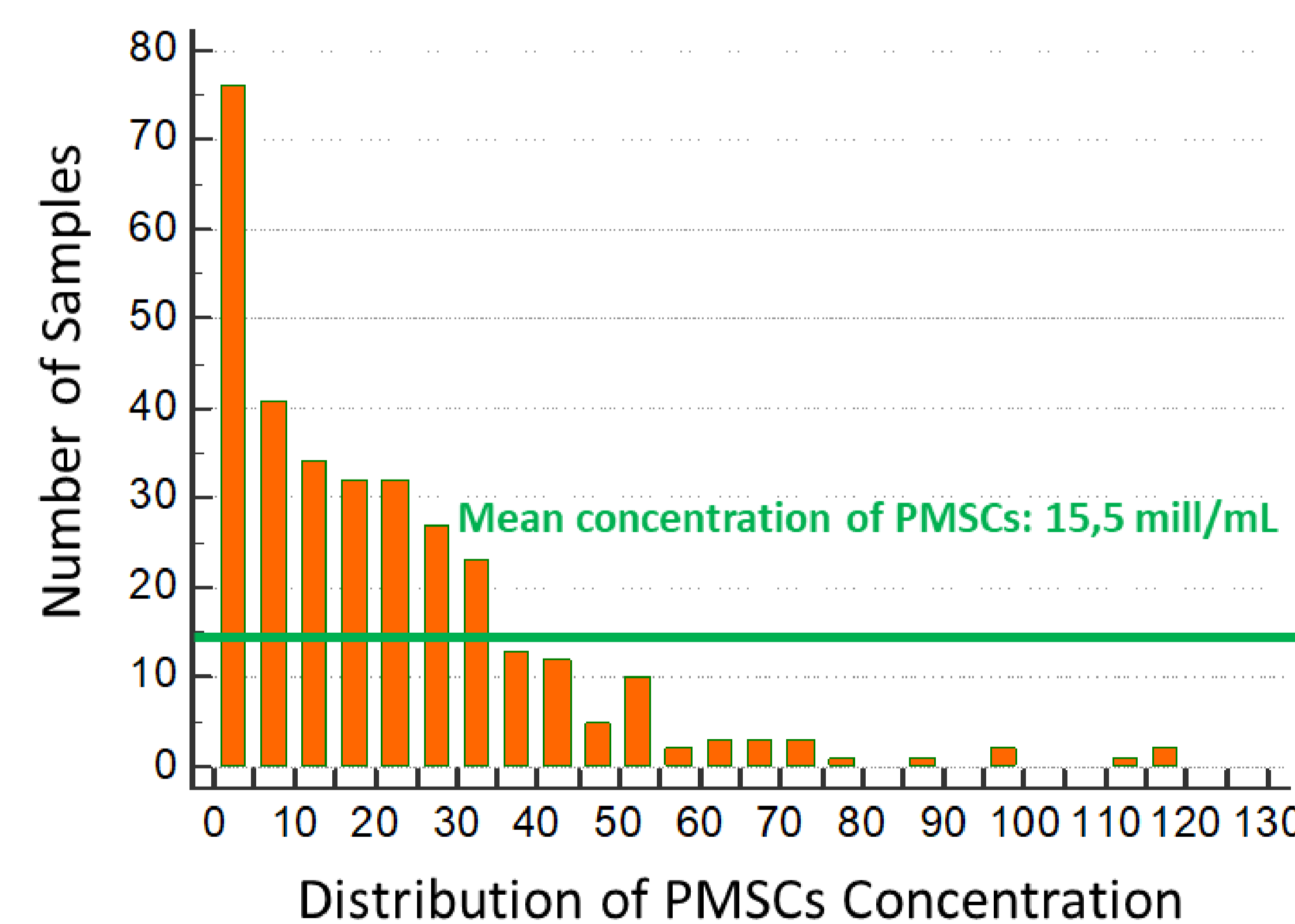
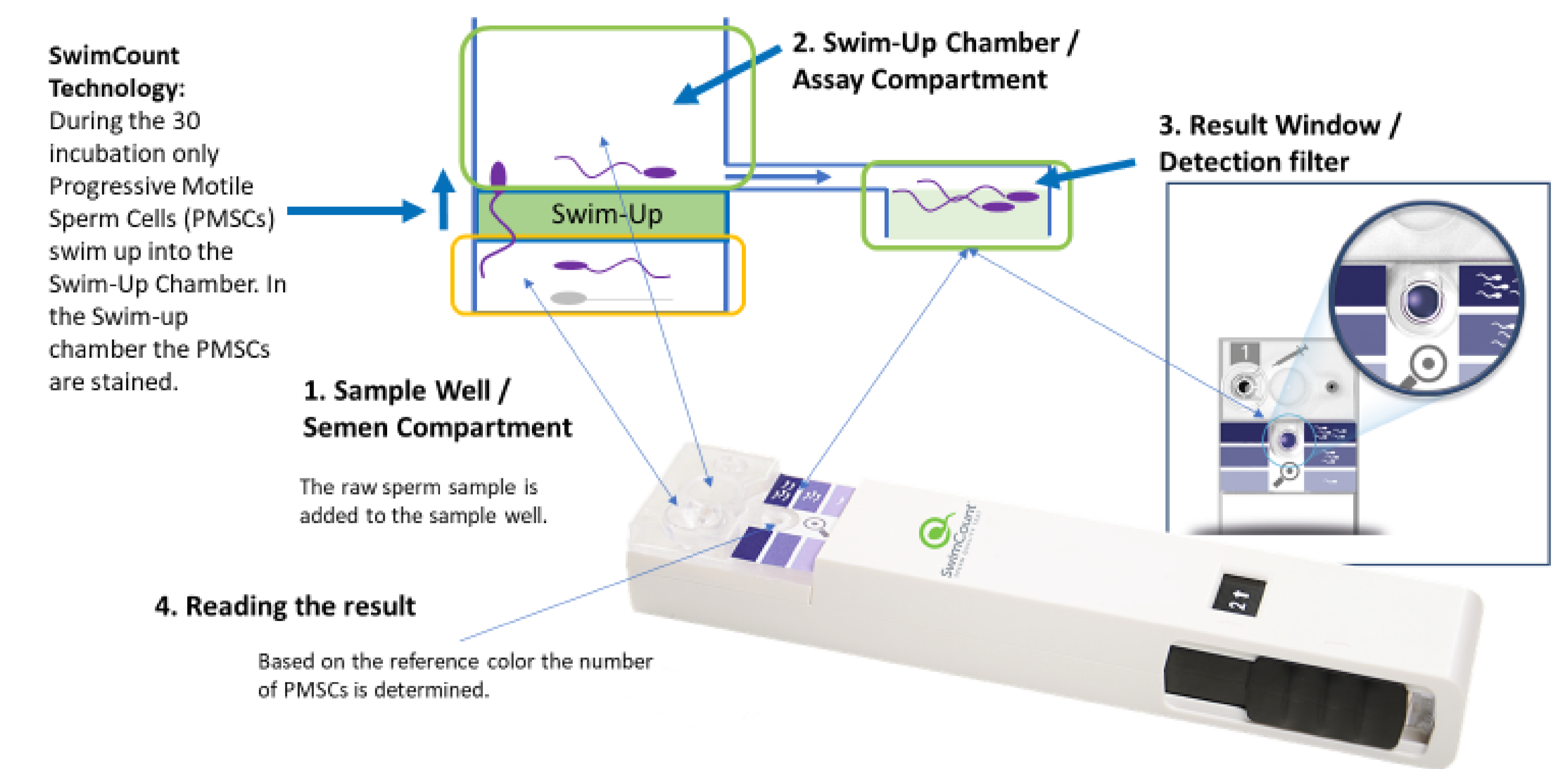
Material and methods

A total of 323 semen samples were included in this multicenter clinical study. All semen samples were analyzed using the Makler counting chamber and compared to the home test kit readout. Semen samples were obtained from men seeking fertility treatment or from sperm donors. Semen samples were allowed to liquefy for a maximum of 30 minutes. We used the Makler counting chamber to know the number of Progressive Motile Sperm Cells (PMSCs). Added 0.5 mL of the sperm sample to the SwimCount test device. Test results were read and categorized as Low, Normal or High PMSCs concentration. ROC curve analysis was used to compare the diagnostic ability or accuracy of the test by using SPSS statistical software.

Results

The test appeared a useful tool for male fertility assessment. The results obtained were compatible with those obtained with conventional sperm analysis. The mean concentration of our sample was 15.5 million of PMSCs/mL. Approximately 23% of the semen samples had a PMSCs count per mL below the threshold of 5 mill/mL, which is considered as subnormal concentration (according to WHO). A good balance between the sensitivity and specificity were obtained at a cut off value of 10.6 mill PMSCs per mL, which gave a sensitivity and specificity of 88.1% and 93.3%, respectively. An area under curve of 0.95 was obtained when the home test performance was compared with traditional semen analysis performed in a standard IVF lab.

SwimCount patented Swim-Up Technology



Conclusion

This kit test can be used as a home screening device for male factor infertility, but it is not a substitute of a standard semen analysis like a specific diagnostic tool for assisted reproduction technology. SwimCount is the first home test which allows patients to get a consistent answer about a potential infertility factor related with higher difficulties to achieve a successful pregnancy.