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Abstract title: Clinical validation of a home test kit for semen quality analysis; comparison with gold standard i.e. conventional sperm counting.

Authors: Virginia García-Láez (IVI Clinic Valencia), Damiá Castello (IVI Clinic Valencia Spain), Prof. Dr. Faruk Buyru (Acibadem Fulya Hospital Istanbul Turkey), Thomas Ebbesen (Nordic Cryobank, Denmark), Annette Gabrielsen (Ciconia Fertility Clinic, Denmark), Marcos Meseguer (IVI Clinic Valencia Spain)

[1]Instituto Universitario IVI Valencia, IVF Laboratory, Valencia, Spain.
[2]Acibadem Fulya Hospital, IVF Laboratory, Istambul, Turkey.
[3]Nordik Cryobank, Andrology Laboratory, Copenhagen, Denmark.
[4]Ciconia Fertility Clinic, IVF Laboratory, Aarhus, Denmark.

Objetive: 75 palabras
The objective of this study was to use a home test kit (SwimCount) as a home screening device or sperm quality test for measure the male fertility. This test works by measuring the sperm cells' ability to swim. Therefore, we can measure the quantity and quality of the semen sample.

Design: 26 palabras.
A total of 323 semen samples were included in this multicenter clinical study.
All semen samples were analyzed using Makler counting chambers and compared to the home test kit readout.

Materials and Methods: 75 o 109 palabras
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. Before counting the number of progressive motile spermatozoa (PMS) using Makler counting chamber, 0.5 mL of the sperm sample was added to the SwimCount test device. Test results were read and categorized as low, normal or high PMS concentration. ROC curve analysis was used to compare the diagnostic ability or accuracy of the test by using SPSS statistical software.

Results: 173 palabras.
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 PMS per mL. Approximately 23% of the semen samples had a PMS count per ml below the threshold of 5mill/ml, which is considered as subnormal concentration (according to WHO). 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. An accuracy of 95% is in the range of excellent agreement.
A good balance between the sensitivity and specificity were obtained at a cut off value of 10.6 mill PMS per mL, which gave a sensitivity and specificity of the of 88.1% and 93.3%, respectively.

Conclusions: 42 palabras.
The results confirmed the usability of the kit test as a home screening device for male factor infertility. It was fast, easy and discreet 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.