The Eeva™ Test

Fact Sheet

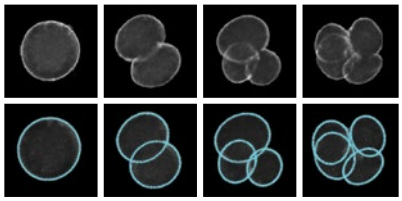
The Eeva™ Test, developed by Auxogyn, is a breakthrough technology designed to give clinicians and their patients a greater level of confidence when choosing embryos to transfer, in an effort to provide women and couples the best chance of a successful pregnancy in their in vitro fertilization (IVF) journey.

Infertility and Treatment with In Vitro Fertilization (IVF)

The Center for Disease Control reports that, in the United States, one out of eight couples is impacted by infertility, and 40% of them seek treatment, many through IVF. Only about one-third of IVF cycles result in live births, many of which are multiples. The U.S. has the **highest rate of multiple births in the world**, at one out of three IVF pregnancies,[1] due to the desire of couples to transfer multiple embryos to increase their likelihood of pregnancy in one cycle.

Embryo Selection During IVF

In current standard practice for IVF, embryos are removed from the incubator at fixed times, viewed manually under a microscope, graded by a clinician based on several visual characteristics and then selected for transfer. This process of visually assessing embryos is known as morphology grading.



A NEW FIRST-OF-ITS-KIND TEST TO AID IN EMBRYO SELECTION

What It Is The Eeva Test is a **non-invasive, first-in-class, FDA cleared, predictive test** that aids embryologists in selecting the embryos with the highest developmental potential during in vitro fertilization (IVF).

How It Works To enhance the morphology grading process performed by embryologists, the Eeva Test takes images of the embryos with the Eeva Scope, a special microscope, every five minutes inside of an incubator. This decreases the time the embryos are exposed to external elements during the incubation period while also collecting valuable embryo developmental information. The images are analyzed by proprietary and automated image analysis software against cell division timing parameters[2] to predict the embryo's developmental potential. During this incubation period, the embryos are cultured in the specially-designed Eeva Dish.

Implications The added information the Eeva Test provides helps embryologists increase their accuracy of predicting embryo developmental potential to aid in selecting the best embryos for transfer. The Eeva Test was designed to provide IVF teams with objective information to select embryos with greater confidence, as they strive to do everything possible to improve their patients' odds of a successful pregnancy.

SUPPORTED BY CLINICAL DATA AND FDA DE NOVO CLEARANCE

In a clinical validation study, a panel of five embryologists from five different clinics used the Eeva Test adjunctively to traditional morphology methods. Their ability to accurately predict embryo development **increased by an average of 53%** over traditional, morphological grading alone.[3] The Eeva Test was cleared by the FDA under the de novo process, a regulatory pathway for select novel, low-to-moderate-risk medical devices that are first-of-a-kind.

The Eeva Test has been commercially available in Europe for over two years, and has been used by thousands of couples. In the United States, in addition to its commercial availability, the Eeva Test is being used in multiple clinical trials and has been featured in major reproductive health peer-reviewed articles such as *Fertility & Sterility and the Journal of Assisted Reproduction and Genetics*.

1. CDC website http://www.cdc.gov/art/ 2. Wong et al, Nature BioTech, 2010 3. Diamond et al, Journal of Assisted Reproduction and Genetics, 2014

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AUXOGYN, INC. 1490 O'Brien Drive, Suite A, Menlo Park, CA 94025 eevacontact@auxogyn.com
Learn more: www.auxogyn.com and www.eevatest.com