The Aurora Test



Oocyte competence prediction

The Aurora Test measures the potential of an oocyte to develop into a normal healthy child after ICSI. After testing the cumulus cells of each oocyte from a woman after hormone stimulation, the embryo from the oocyte with the highest potential will be transferred into the uterus.

Applying this technology in IVF practice has shown that pregnancy rates have doubled (from 29% to 61%) and live birth increased from 27% to 50% after transfer of a single embryo on day 3.

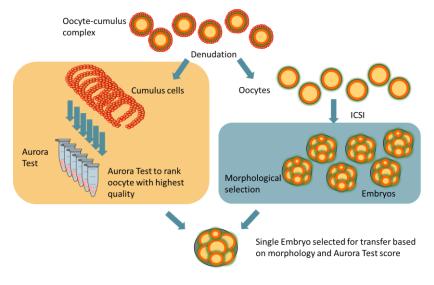


Figure 1. Aurora Test principle

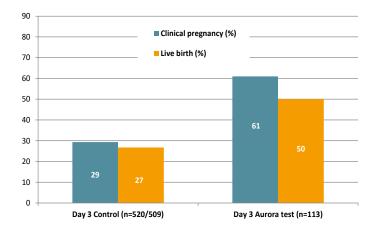
Aurora Test principle

The Aurora Test is performed on cumulus cells from all oocytes from a patient. The test is based on the measurement of five specific gene expressions.

Cumulus cells are isolated from all oocytes and RNA is then extracted from the cumulus cells for each of the harvested oocytes. cDNA synthesis and real-time PCR is done using 3 predictive genes and two control genes. PCR results lead to a ranking for all oocytes.

Pregnancy rate doubled from 29% to 61% in a prospective clinical trial in Europe

- Two arm study: Aurora test arm with day 3 SET and a control arm with day 3 SET without Aurora Test
- 113 tested patient (majority Caucasians and some Arab patients) and 520 control patients
- Age 22-39 years of age, good ovarian response, no severe male infertility
- Stimulated by HP-hMG (Menopur) and single-embryo transfer (SET) policy



Inclusion criteria

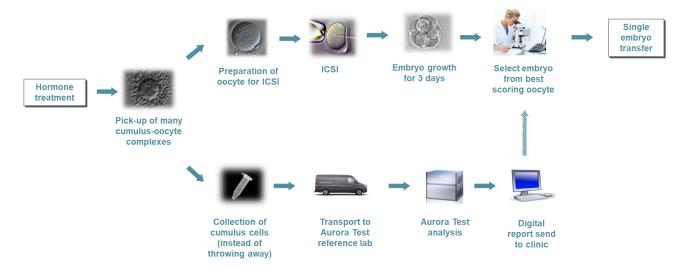


The application of Aurora Test is validated for patients with the following criteria:

- · Stimulation with HP-hMG hormones (e.g. Menopur) followed by ICSI
- Patient age between 22 to 39 years, good ovarian reserve, excluding severe male infertility
- Single embryo transfers on day 3 (fresh or frozen) to avoid twin birth

Test service offered

- DAY 0: cumulus-oocyte complex pick-up. Cumulus cells must be removed for each oocyte by embryologist and individually collected into bar-coded tubes.
- DAY 0-1: Samples will be transported to a clinical testing lab nearby which runs the Aurora Test
- DAY 1-2: Aurora Test (RNA isolation, QPCR and analysis) is done in the clinical testing lab.
- DAY 2-3: Clinical testing lab will communicate Clinical Report to IVF clinic. Report gives a ranking of all oocytes and specifies which cumulus-oocyte complex has the best score.
- DAY 3: Embryologist uses this score besides his morphological evaluation to select the best embryo for transfer.
- In case there is no pregnancy from a first transfer, the supernumerary embryos which were vitrified will also be transferred following the score.



In the future, the Aurora Test application will be broadened to other gonadotrophins.

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