



Sperm DNA Decondensation Test (SDDSM Test)

WHAT IS THE SDD TEST?

- ❑ The SDD Test is used to identify patients whose sperm are incapable of normal *decondensation* and, therefore, proper embryonic development.

Only commercially available *in vitro* sperm function test for evaluating a critical post-fertilization sperm activation event, i.e., decondensation of the sperm chromatin, in a **controlled, physiologically relevant environment***

* The SDD Test is one part of the Human Sperm Activation Assay (HSAA); an *in vitro* sperm function test that can evaluate sperm activation events including: decondensation, DNA synthesis, and recondensation^{1,2} Patent numbers: 5,358,847, 5,770,363, and 5,919,621 (+ 2 Patents Pending).

WHAT CAN THE SDD TEST DO FOR YOUR CLINIC?

- ❑ Improve your clinic's live birth rates for IUI, IVF and ICSI!

WHAT CAN THE SDD TEST DO FOR YOUR PATIENTS?

- ❑ With better direction in treatment, patients will bring babies home sooner and suffer less emotionally and financially!

INDICATIONS FOR TESTING (SUGGESTED):

- 1) Initial diagnostic evaluation prior to first ART attempt; &
- 2) Use as a screening tool to rule out male-factor(s) from the start

ART METHOD SELECTION & SDDSM TESTING

- ❑ SDD Normal ($\geq 80\%$ of Fertile Control) = *Successful outcome in IUI, IVF, and ICSI!*
- ❑ SDD Abnormal ($<80\%$ of Fertile Control) = *Poor/Low chance for IUI/IVF success + Normal ICSI success!*

CLINICAL EVIDENCE

- ❑ SDD is abnormal in 27% of infertile men
- ❑ SDD Testing differentiates between IUI/IVF and ICSI chances for live birth outcome

Study 1: Age matched, blinded study of 74 idiopathic males whose sperm from a sample used in either an IUI, IVF, or GIFT attempt at pregnancy and 74 fertile males were evaluated in the SDD Test^{1,2} **RESULTS:**

- ❑ 13 of 74 (18%) idiopathic males found to be infertile with 0% live births
- ❑ 73 of 74 (98.6%) fertile males retained normal SDD capacity
- ❑ This demonstrates the consistency of the male's fertilization capacity over time

Study 2: Retrospective study of 58 patients, the outcomes of the first IUI or IVF attempt subsequent to an SDD Test were determined³ **RESULTS:**

- ❑ 43 of 58 patients with normal scores; 12 of 43 (28%) had live births from IUI or IVF attempts at pregnancy (same sample used in an IUI or IVF attempt at pregnancy was evaluated in the SDD Test)
- ❑ 15 of 58 patients with abnormal scores; 0 of 15 (0%) had live births from IUI or IVF attempts at pregnancy
- ❑ The SDD Test is predictive of IUI and IVF live birth outcome ($p = 0.025$)

Study 3: Prospective, blinded study of 50 patients, the outcomes of the first ICSI attempt subsequent to an SDD Test were determined^{4,5} Note: After performing the SDD Test, sperm was frozen until used in an ICSI attempt at pregnancy **RESULTS:**

- ❑ 30 of 50 patients with normal scores; 43% had live births
- ❑ 20 of 50 patients with abnormal scores; 45% had live births
- ❑ The SDD Test is NOT predictive of ICSI outcome ($p \gg \gg 0.05$)!

WHAT DO THESE RESULTS TELL US?

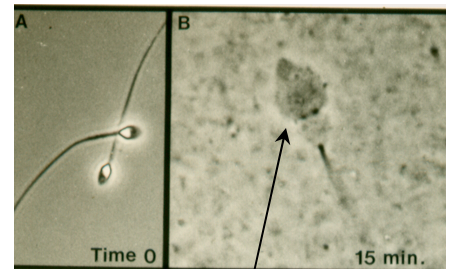
If the patient has an abnormal SDD Test score, their **ONLY** option is ICSI; they can eliminate IUI and IVF attempts that will have a poor chance of successful live birth(s).

HOW DOES THE SDD TEST WORK?



Unfertilized *Xenopus laevis* eggs are collected and after centrifugation, the extract layer above the dark egg pellet, and below the light yellow yolk layer is removed and used to perform the SDD Test

- Permeabilized sperm are mixed with the frog egg extract
- The decondensation rate of 50-100 sperm from both a fertile male and patient are measured in real time after mixing the sperm and the frog egg extract
- Results are reported as the percentage of patient sperm that have fully decondensed during the 15-20 minute scoring window relative to the fertile male control sperm
- Normal: 80-100% of Control (Fully Decondensed)
- Abnormal: < 80% of Control (Fully Decondensed)



Fully Decondensed Sperm in Egg Extract – A & B same scale

FOLLOW UP OR TREATMENTS BASED ON THE SDD TEST RESULTS

Normal Results ($\geq 80\%$)

- Neither the initial or follow up specimens were associated with reduced live birth outcomes for any ART method

Abnormal Results (< 80%)

- ICSI treatment earlier in the treatment protocol, or as the method of choice
- Inquiry into possible exposures to occupational and/or environmental reproductive toxicants, medications, alcohol, tobacco products and/or drugs of abuse (see addition handouts)
- If possible, remove patient from such exposure(s) and re-evaluate sperm in the SDD Test 3 months post-exposure(s)
- Send patient to urologist; if patient has varicocele(s), recent unpublished data suggests that such a patient may benefit from a varicocelectomy. Studies are in progress to verify our initial findings.

REFERENCES

1. Brown DB and Nagamani M. Use of *Xenopus laevis* frog egg extract in diagnosing human male unexplained infertility. *Yale J of Biol & Med* **1992**; 65:29-38
2. Brown DB *et al.* Some cases of human male infertility are explained by abnormal *in vitro* human sperm activation. *Fert & Steril* **1995**; 64(3):612-622
3. Anderson A *et al.* Sperm DNA decondensation assay and selection of assisted reproductive technology method. ASRM October **2007** Abstract
4. Merryman DC, Rivnay B, Honea KL and Brown D. Sperm DNA Decondensation (SDD) and Sperm Penetration Assay (SPA) with Gradient Preparation Are Not Predictive of Pregnancy Outcome in In Vitro Fertilization (IVF) cycles with Intracytoplasmic Sperm Injection (ICSI) ASRM October **2007** Abstract
5. Brown DB, Merryman DC, Rivnay B, Long CA, Houseman VL and Honea KL. Manuscript in Preparation

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