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. 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 ( > 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.

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 determined.

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. 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>>>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?

- 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)

FOLLOW UP OR TREATMENTS BASED ON THE SDD TEST RESULTS

Normal Results (≥ 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

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