The panel results indicate that ICSI should be considered early in the selection of infertility treatment options. The abnormal SDD™ score indicates that the semen provided would have a lower than normal likelihood of success if used in IUI or conventional IVF but normal success rates with ICSI. The abnormal SDFA™ test result indicates that the semen provided would have a much lower than normal likelihood of success if used in IUI, and that ICSI will be more successful than normal when compared to conventional IVF.

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**Sperm DNA Decondensation Test (SDD™)**

**Science and Physiology:** The SDD™ test evaluates the ability of sperm DNA to unwind or “decondense” which is necessary during fertilization. In normal fertile males, 95% of sperm show complete decondensation after a 15 minute incubation in simulated egg extract. Abnormal semen shows less than 80% of sperm decondensing during the same interval. It is thought that this difference is due to sperm DNA damage.

**Clinical Data:** Clinical research indicates that abnormal SDD™ scores predict low chance of success with IUI and IVF but not ICSI. Four prospective blinded studies performed in the 1990s with a total of 152 infertile men demonstrated that 20% had abnormal SDD™ scores and no success with IUI, IVF, GIFT, or ICSI while only 1.4% of fertile men (n=74) had abnormal SDD™ scores. In a recent retrospective study, zero of 15 patients with abnormal SDD™ scores had success with the next IUI or IVF attempt while 43 patients with normal SDD™ scores had industry standard success rates with IUI and IVF. However, a recent prospective study (n=50) demonstrated that SDD™ abnormal men have normal success rates using current ICSI methodology, which was also observed in an additional study (n=150, manuscript in preparation). Further confirmatory studies are underway.

**Sperm DNA Fragmentation Assay (SDFA™)**

**Science and Physiology:** The SDFA™ test evaluates the amount of broken (fragmented) DNA in sperm by staining sperm with a fluorescent dye, called acridine orange, which glows red when bound to broken DNA and green when bound to normal DNA. Five thousand sperm are analyzed and the ratio of red to green (broken to normal DNA) is measured and reported as a DNA fragmentation index (DFI).

**Clinical Data:** Clinical research indicates that abnormal SDFA™ scores predict poor chance of success with IUI but improved ICSI success relative to conventional IVF than normally observed. Recent research with about 1000 cycles of ART (IUI, IVF, and ICSI) demonstrated that semen with abnormal SDFA™ results had a 98.5% chance of failing IUI but noted that live delivery rates with ICSI were double those of conventional IVF.

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**References**

1. Anderson A et al. Sperm DNA decondensation assay and selection of assisted reproductive technology method. ASRM May 2007 Abstract
3. 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 May 2007 Abstract