# **Stem Cell-based Therapy for Male Infertility**

TECHNOLOGY NUMBERS: 2021-502, 2024-053, 2025-659



## **Technology ID**

2021-502

## Category

Research Tools and Reagents Life Sciences Accelerate Blue Foundry -2025/Life Sciences

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## **Accelerate Blue Foundry - 2025 (Life Sciences)**

## **OVERVIEW**

Y-Reproductive Technologies has engineered miniature human testis from induced pluripotent stem cells to generate sperm in a dish, offering the only path to biological fatherhood for men who currently have no options.



## **DESCRIPTION**

The current standard of care for men with no sperm is a procedure termed microdissection testicular sperm extraction (microTESE), a highly invasive surgical procedure used to hunt for possible pockets of viable sperm within the testis. The success rates for this procedure are low (~30%) and highly variable from center to center, and many men endure surgery only to be told they have no options for biological paternity. In short, today's approaches are invasive, unreliable, and for the majority, a dead end. To overcome this fate, experimental attempts have been made to generate sperm cells from induced pluripotent stem cells (iPSCs), but these efforts have stalled because sperm cell precursors cannot be matured into functional sperm without the 'nursery,' an biologically optimized microenvironment that is required for their development. Stem cells without the right nursery microenvironment do not develop to viable sperm. Y-Reproductive Technologies has built a miniature, engineered human testis nursery with the essential architecture and appropriate molecular signals to transform immature germ cells into sperm.

#### **VALUE PROPOSITION**

We have engineered the first miniature human testis to solve male infertility. Our system is safe, efficient and scalable. We use off-the-shelf engineered tissue produced from pluripotent stem cells. Once in operation, our clinic will accept patient samples by mail and return IVF-ready sperm. We can accept either patient-derived germ cell precursors or a blood sample, suitable for in vitro-derived germ cells. By enabling sperm cell generation outside the body, our technology turns an impossible path to biological parenthood into a tractable, scalable treatment - bringing biological fatherhood within reach for hundreds of thousands of men where medicine currently has nothing to offer.

## **TECHNOLOGY READINESS LEVEL**

# **Therapeutics Technology Readiness Levels**



#### **INTELLECTUAL PROPERTY STATUS**

Patent applications pending.

## **MARKET OPPORTUNITY**

Infertility is a growing global crisis, yet innovation has focused almost exclusively on womeneven though men contribute to 50% of infertility diagnoses. Roughly 1% of reproductive-age men worldwide, including ~580,000 in the U.S., fail to produce any viable sperm in ejaculate. Of these, ~75,000 men pursue IVF annually, and are subject to invasive testicular biopsy procedures to find sperm, with high costs and devastating failure rates. These men have no options for parenthood except donor sperm or adoption. Despite hundreds of millions invested into female-focused reproductive startups, men remain underserved. At Y-Reproductive Technologies, we are solving this problem by generating sperm outside the body – paving the first viable path to biological fatherhood for these men. In addition to its application for clinical fertility restoration, this technology will be valuable for research models for reproductive biology and for high-throughput screening platforms for male contraceptives or toxicology. Pharmaceutical R&D and regenerative medicine are attractive, high-value industries that can benefit from reliable, human-derived organoid models for both drug development and cell therapy. Additional opportunities exist in biobanking, personalized medicine, and academic discovery, wherever robust human tissue models are required.

The demand for effective infertility solutions and the limitations of animal models are driving strong investment and innovation in tissue engineering and organoid platforms, with the global infertility treatment market expected to surpass \$33B by 2030.