Introduction

Over the past 20+ years, technological advancements in the fields of single-cell genomics and IVF embryo handling have made it possible to accurately assess the chromosomal copy number (PGT-A/SR) and/or disease status (PGT-M) of human embryos prior to transfer into the prospective mother or surrogate.1,3,4,5

In 2019, CooperSurgical® Fertility Solutions exhibited its leadership in the PGT-A market with the launch of PGTai® 2.0, the first technology to leverage both genome-wide copy number variations (CNV) and single nucleotide polymorphism (SNP) assessment to fully evaluate the copy number of an embryo. Furthermore, if combined with information from the parental genomes used to create the embryo, the PGTai® 2.0 technology further leverages SNPs to accurately identify the parental origin of meiotically derived aneuploidies in the embryo.

Through continued assay and bioinformatics innovation, along with enhanced sequencing capabilities, our new PGT-Complete offering now assesses parental genome inheritance patterns in a trophectoderm biopsy. This added analysis is called Parental Quality Control (PQC). This additional analysis helps provide confidence in the genetic relatedness of the embryo biopsy with its intended biological parents/gamete sources.

The following pages describe the validation and performance of the Parental QC analysis and its importance in quality control for pre-biopsy embryo culture and downstream PGT-A.

Highlights

• Our innovative PGTai® 2.0 technology is improved with simultaneous analysis of parental inheritance during PGT-A for embryo biopsies in PGT-Complete

• This sophisticated analysis leverages information from parental and embryonic genomes to provide more confidence that the embryo biopsy has the expected (maternal & paternal) genetic contribution

• This cutting-edge analysis is powered by our artificial intelligence (AI) and allows us to accurately identify inheritance patterns

• This test is now available as part of our PGT-Complete, a 4-in-1 genetic test that provides a new standard of care in PGT

PGT-Complete

Four-in-one genetic test to advance the standard of care

• Includes PGT-A and all the benefits of our innovative and proprietary AI to help improve the chances of IVF success

• Parental QC helps reduce parental anxiety of potential mix-ups and provides reassurance that the intended gametes were used

• Origin of aneuploidy information supports the clinic and patients to guide future gamete donor decisions

• Genetic PN check provides the capability to identify and rescue true 2PN embryos and might enable additional embryo transfers1

A four-in-one genetic test for the most complete clinical insights

NEW: REASSURANCE THAT AN EMBRYO BIOSY INHERITED THE EXPECTED PARENTAL GENOMES

For a full review of our PGTai® 2.0 technology please see our white paper

1. JBRRA Assist Reprod. 2020 Apr-Jun; 24(2): 143–146. Blastocysts Derived From 0PN Oocytes: Genetic And Clinical Results


Maternal and paternal inheritance assessment with PQC

ParentalQC was developed using 189 Trios (maternal DNA + paternal DNA + embryo biopsy) from 42 families with expected inheritance patterns. These were determined by PGT-M analysis that utilized genome-wide SNP analysis (Karyomapping). As part of the Trio selection, both families with and without known consanguinity were included in the development process to ensure the algorithm’s robustness in various circumstances.

Parental genomic DNA (gDNA) obtained from buccal swabs and DNA from embryo biopsies were processed through our PGT-A workflow and analyzed for CNV by the PGTa®2.0 algorithm. Embryo biopsies, regardless of ploidy status, were analyzed alongside ParentalQC was developed using 189 Trios (maternal DNA + paternal DNA + embryo biopsy) from 42 families with expected inheritance patterns. These were determined by PGT-M analysis that utilized genome-wide SNP analysis (Karyomapping). As part of the Trio selection, both families with and without known consanguinity were included in the development process to ensure the algorithm’s robustness in various circumstances.

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The CooperSurgical® Difference
Reassure, Empower, Safeguard

At CooperSurgical we understand the need for the utmost traceability and transparency for all stages of the patient journey and therefore we also offer our RI Witness™ solution.

Parental QC and RI Witness complement each other perfectly to provide a market-leading solution for clinics to help prevent mix-ups, and to provide a powerful tool to externally demonstrate the robustness of their protocols, as well as significantly reduce parental anxiety of mix-ups with a simple genetic confirmation.

- RI Witness is a market-leading electronic witnessing system used to help prevent mixups in the IVF laboratory and ensure adherence to set SOPs supporting the overall IVF laboratory management
- Parental QC (which is part of our innovative PGT-Complete test) is designed to provide patients reassurance that the intended egg and sperm were used, and to help reduce parental anxiety of potential mix-ups
- Both Parental QC and RI Witness can be used by the clinic to demonstrate to their customers the extra steps they take to help safeguard patients’ samples and offer full transparency and an audit trail

At CooperSurgical Fertility Solutions, we are very proactive in ensuring the best overall service to our clients and hence their patients through innovation and this is reflected in our most comprehensive PGT-A platform yet.

PGT-Complete, setting the new standard of care in PGT.