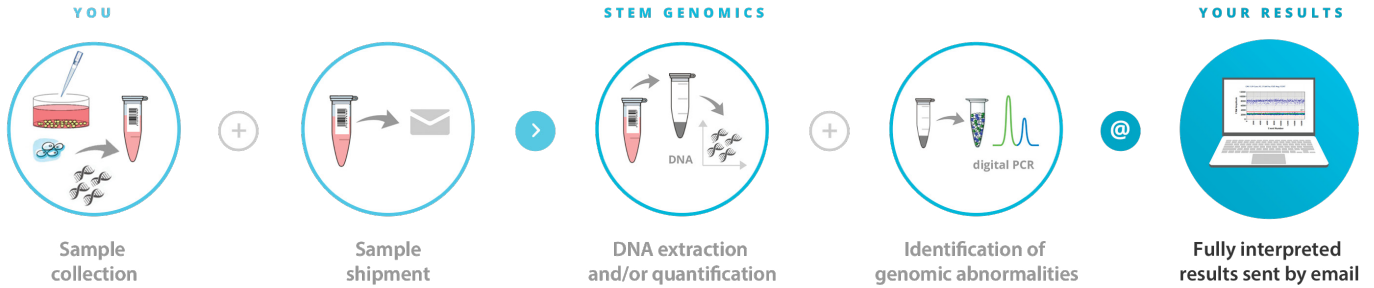


SOLUTION

iCS-digital™ PSC

The iCS-digital™ PSC test detects more than 90% of recurrent genomic abnormalities in human pluripotent stem cells (hPSCs).



CELL TYPES	STAGES	SAMPLES	SHIPMENT	COVERAGE	MOSAICISM	TIME
Human PSCs: ESCs & iPSCs	- Reprogramming - Derivation - Maintenance - Differentiation - Gene editing	- gDNA - Cell pellet - Cells in fresh culture media (or in cell culture supernatant)	- Room temperature - Dry ice - Room temperature	Test with 24 probes : 91% of recurrent abnormalities Test with 12 probes : 76% of recurrent abnormalities Test the 20q 11.21 region : the most common genomic abnormality in hPSCs (>20%)	>20% (depending on sample quality)	2-3 days after sample reception

DEFINITION OF RECURRENT GENOMIC ABNORMALITIES AND RATIONALE FOR REGULAR TESTING

In culture, human pluripotent stem cells (hPSCs) may develop recurrent genomic abnormalities. These defects, essentially copy number variations (CNVs), are a major concern because they reflect a selection pressure that may favour hPSC proliferation and survival, or reduce their differentiation capacities*.

We specifically analysed the data from 100 scientific publications concerning 942 hPSC samples. After exclusion of polymorphic variants, we highlighted the presence of 738 recurrent genetic abnormalities (i.e., genomic defects found in at least five different publications).

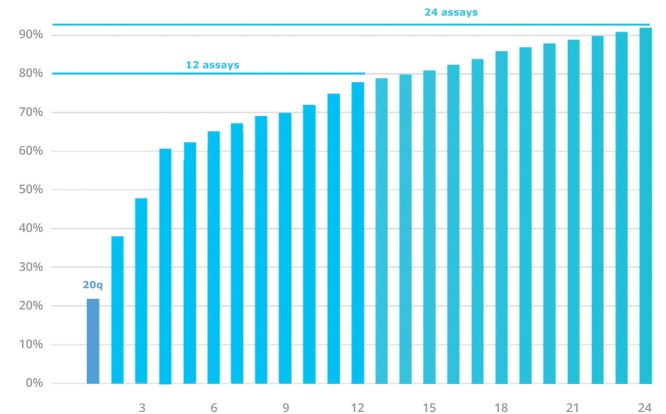
We then used these data to develop the iCS-digital™ PSC test. This assay includes a set of 24 specific probes that were designed and optimized based on the most reported altered sequences and that allows detecting, by digital PCR, more than 90% of recurrent genetic abnormalities in hPSCs. Our test portfolio also includes :

- a 12-probes version of the iCS-digital™ PSC test allowing the detection of 76% of the recurrent genetic abnormalities,
- a single-probe test version specifically dedicated to the sub-karyotypic 20q11.21 amplification detection.

The test is published in Stem Cell Reports**.

Thanks to the simplicity of the collection method and the rapidity of the analysis, the iCS-digital™ PSC test is a straightforward method for monitoring cell lines at regular intervals in culture, for controlling the cells before initiating critical and costly steps (banking, differentiation), and for screening hPSC clones after reprogramming or gene editing.

Percentage of cumulated recurrent abnormalities detected in function of the number of probes targeting specific genomic sequences



* Assessing the Genome Integrity of Human Induced Pluripotent Stem Cells: What Quality Control Metrics? Stem Cells 2018 Jun;36(6):814-821.

** Recurrent Genetic Abnormalities in Human Pluripotent Stem Cells: Definition and Routine Detection in Culture Supernatant by Targeted Droplet Digital PCR. Stem Cell Reports 2020 Jan 14;14(1):1-8.

The iCS-digital™ PSC test is a non-invasive tool to detect the vast majority of recurrent genomic abnormalities for the routine monitoring of human PSC genomic stability. This new test can change how quality control is implemented for PSC use in basic research and regenerative medicine.