

clean cells

SOLUTION FOR BIOLOGICS

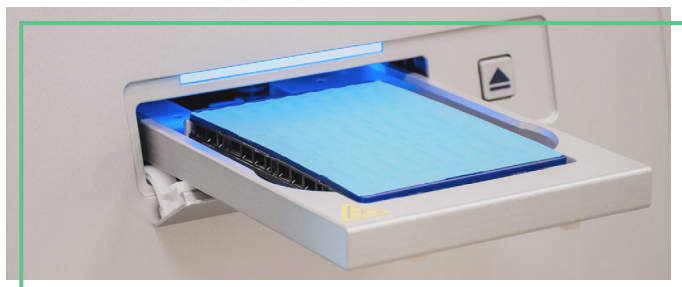
DIGITAL PCR

applied to the quality control
of your biologics

DIGITAL PCR IN GMP GRADE

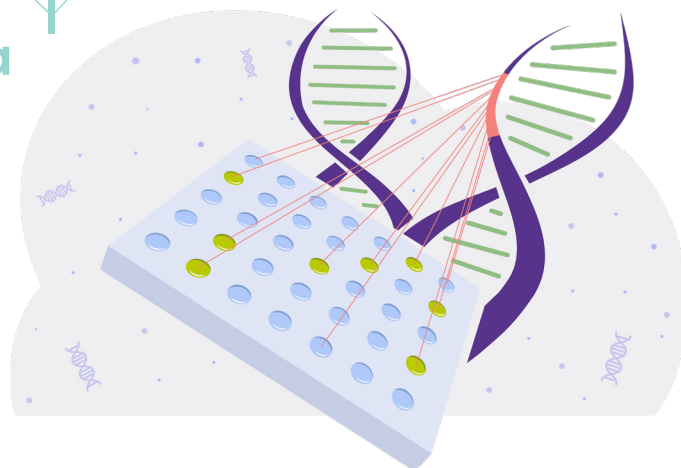
Clean Cells completes its range of tools to support the characterization of biological products with the acquisition of a digital PCR platform (Qiagen 2019). This new standard of dPCR is using **physical partitioning**, granting high quality and robust results through automation. The 4 main steps are: sample dilution, partitioning, PCR amplification and readout.

Already in use in a GMP context, we support our partners in the accurate characterization of their products, particularly for their regulatory needs.



OUR APPROACH & REGULATORY COMPLIANCE

At Clean Cells we provide a customized support. We can adapt our in house biomolecular methods, or develop new assays from scratch, all the way to a GMP-compliant QC assay for post-market authorisation (ICHQ2R1, equipment CFR21 part 11).

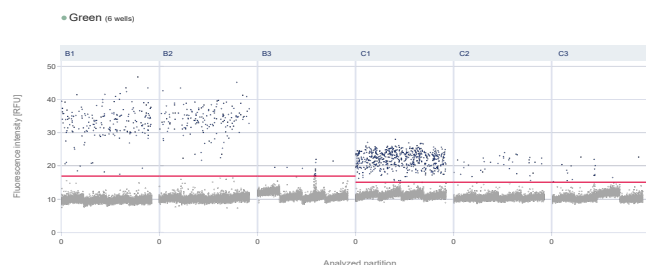


WHAT CAN DIGITAL PCR DO FOR YOUR QUALITY CONTROL?

We can use digital PCR for assays that require absolute quantification, high sensitivity and low limit of quantification such as:

- Gene/plasmid copy number
- Viral titration for viral vectors or for seed stocks
- Quantification of translocations in modified cells
- Gene expression
- Host cell DNA quantification

The dPCR method is complementary tool to a TCID50 (infectious titration), a FISH analysis, or a clonality study (number of transgene copies).



As an expert of dPCR and qPCR, Clean Cells supports any needs that you have for the characterization and release of your products.