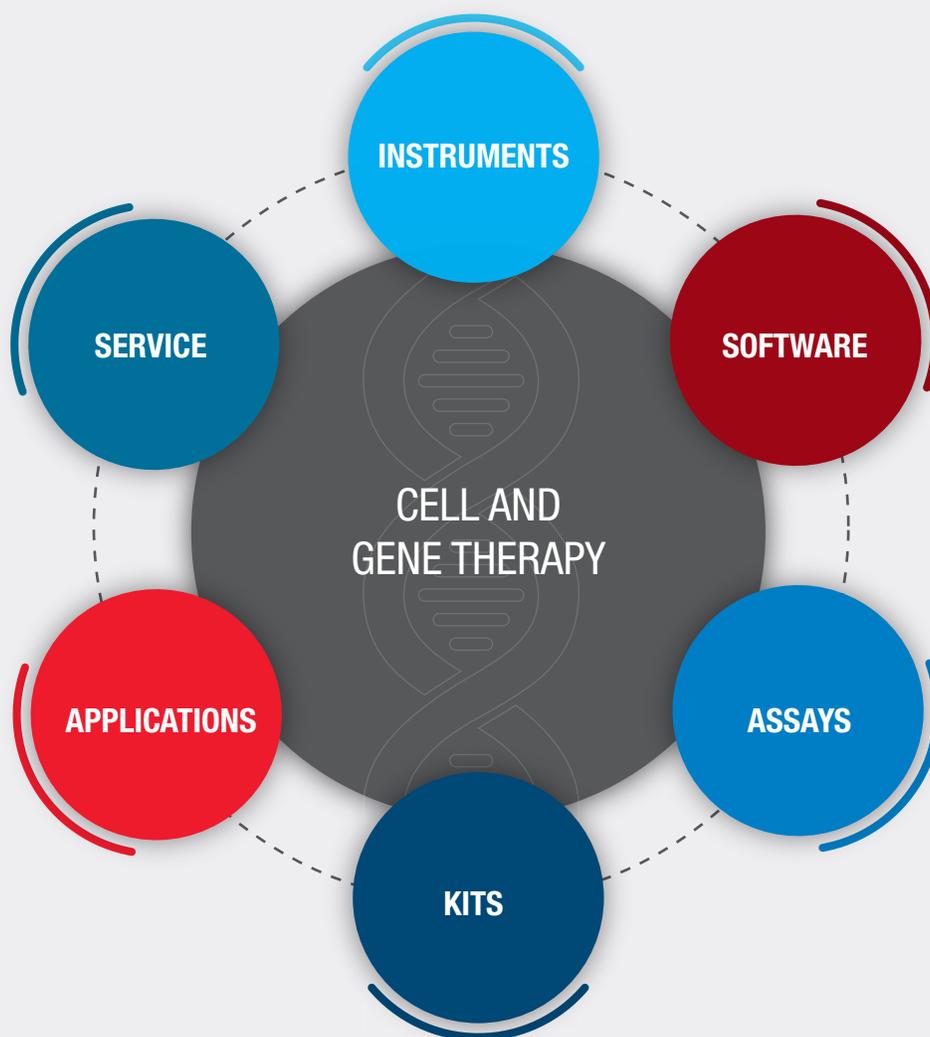


Quality Control Solutions for Cell and Gene Therapy

Your Partner from Discovery to Therapeutic



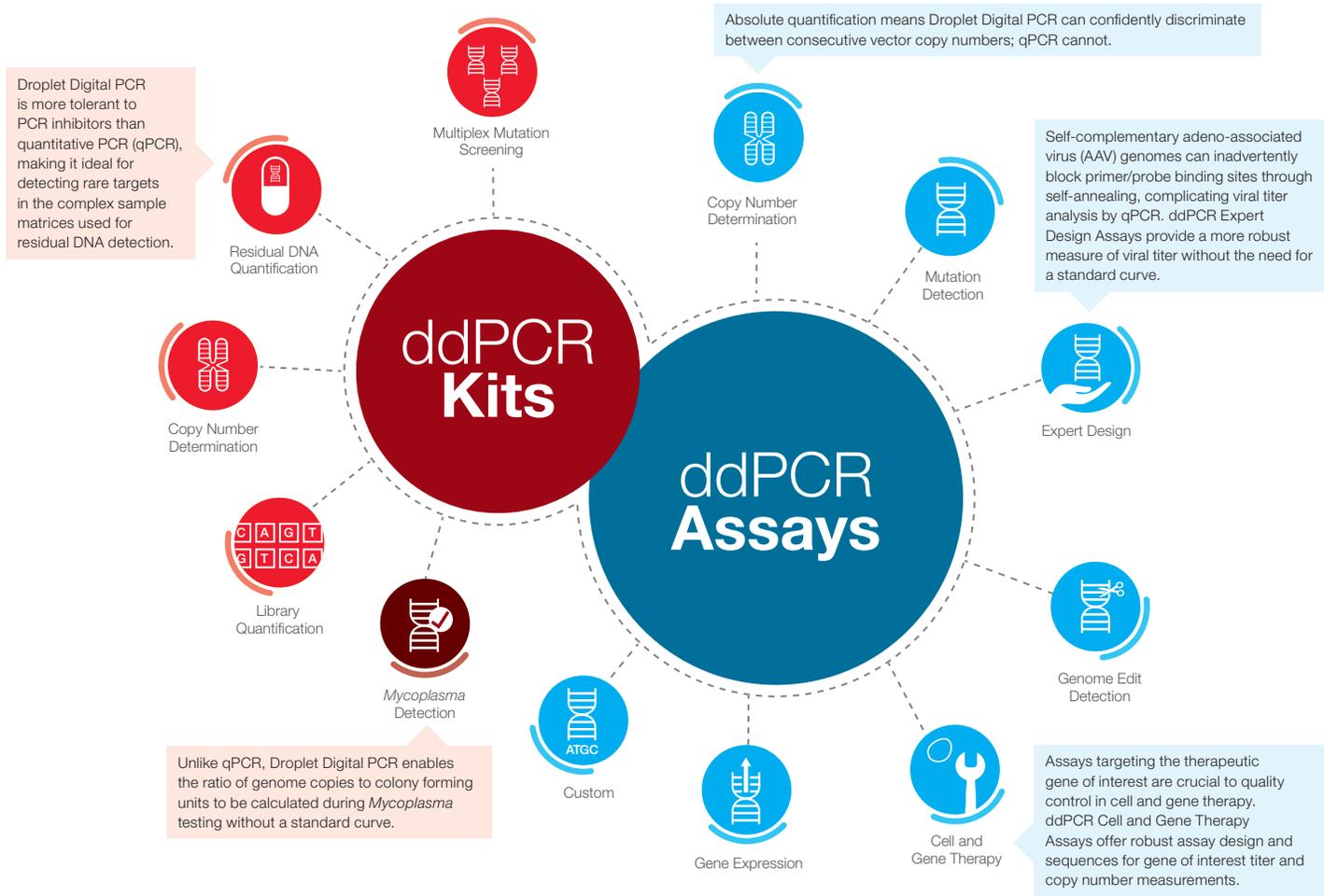
Unrivaled Precision and Accuracy for Cell and Gene Therapy



Droplet Digital PCR (ddPCR) provides highly precise and absolute quantification of nucleic acids by counting nucleic acid molecules encapsulated in discrete water-in-oil droplets. Digital measurement of nucleic acids using Droplet Digital PCR is suitable for the analysis of both in-process samples and final drug products due to the technology's tolerance to PCR inhibitors. This tolerance to formulation matrices enables the implementation of Droplet Digital PCR throughout the entire manufacturing process. Bio-Rad ddPCR Systems utilize a simple workflow with minimal hands-on time while reducing sample replicates and user-to-user variability.

ddPCR Assays and Kits for Cell and Gene Therapy

Bio-Rad offers a comprehensive portfolio of ddPCR Assays and Kits for numerous applications, including mutation detection, copy number determination, genome edit detection, gene expression analysis, *Mycoplasma* detection, multiplex mutation screening, residual DNA quantification, and library quantification.



Find and Buy Your Assay

Browse Digital Assays

Find and Buy Your ddPCR Assay

Take advantage of 24/7 service to find, design, and buy an assay in three steps:

- 1 Choose your application or search by unique assay ID
- 2 Enter target or sequence information
- 3 Pick a size and add to your cart



Assay Design Service
Click the icon to obtain assistance with assay design from our ddPCR specialists.



Interactive Infographic
Click the icon to find ddPCR Assays and Kits for your cell and gene therapy application.

Gene Therapy

Developing effective and reproducible gene therapies requires the use of sensitive and robust testing methods, such as Droplet Digital PCR, to validate the quality of the therapeutic product. Bio-Rad offers a portfolio of ddPCR viral quantification solutions for the accurate, precise, and robust measurement of viral titer in a sample. Scientists may also use some of these solutions to perform quality checks on incoming plasmids and to conduct gene therapy biodistribution studies.



- Perform plasmid quality checks using Expert Design Assays



- Create Custom ddPCR Assays for plasmid quality checks using the Cell and Gene Therapy Design Engine



- Leverage Expert Design Assays to get robust viral titer measurements



- Create Custom ddPCR Assays for viral titer measurement using the Cell and Gene Therapy Design Engine



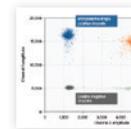
- Learn more about our complete ddPCR workflow solution for AAV vector genome titer



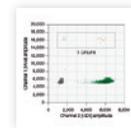
- Achieve absolute quantification of residual host DNA using ddPCR Residual DNA Quantification Kits. The sensitivity of Droplet Digital PCR ensures adherence to the U.S. Food and Drug Administration (FDA) guideline of <100 pg host DNA per dose



- Reduce false positives with the VeriCheck ddPCR *Mycoplasma* Detection Kit



- Learn how to transition to Droplet Digital PCR from qPCR for *Mycoplasma* testing



- Evaluate the biodistribution and transgene production level of your cell therapy using our Expert Design Assays

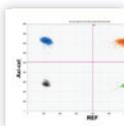
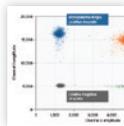
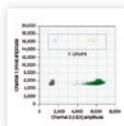
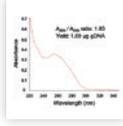


- Design custom ddPCR Assays for your gene of interest using our Assay Design Engine



Cell Therapy

Development, validation, and implementation of robust and accurate methods are vital to test the safety and efficacy of gene-modified cell therapies such as chimeric antigen receptor (CAR) T cells. Droplet Digital PCR offers absolute quantification of transgene copy number in a sample. This method can be used to effectively quantify CAR copy numbers in transfected or transduced T cells or count the number of cells that contain the transgene of interest. This is especially important for transgenes that cannot be detected by antibodies. The ddPCR whole-cell DNA workflow is a reproducible and easy way to measure the percentage of edited cells with minimal input cells and can be applied at multiple steps during the cell therapy manufacturing process.

In-Process Testing			Final QA/QC			Patient Monitoring
Incoming Vector	Activate and Transduce T Cells	Prepare Final Cell Dose	Potency	Purity	Safety	Verify Therapeutic Delivery and Expression
Plasmid Quality 	Transgene Expression 	Vector Copy Number 	Residual DNA 	Mycoplasma 	Gene Expression 	
<ul style="list-style-type: none"> Perform plasmid quality checks using Expert Design Assays  <ul style="list-style-type: none"> Create Custom ddPCR Assays for plasmid quality checks using the Cell and Gene Therapy Design Engine 	<ul style="list-style-type: none"> Verify transgene expression for anti-CD19 CAR-T cells using the CAR-T CD19 Monitoring Assay 	<ul style="list-style-type: none"> Quantify genetic modifications in whole cells using whole-cell Droplet Digital PCR. This protocol allows cell counting by encapsulating whole cells and targeting the transgene and reference gene to amplify the DNA within  <ul style="list-style-type: none"> Learn how Fehse et al. (2020) developed a ddPCR Assay for precise quantification of anti-CD19 CAR-T cells down to 0.01% frequency from patients treated with axicabtagene ciloleucel (axi-cel)  <ul style="list-style-type: none"> Click to watch the webinar: In-vivo monitoring of CAR-T cells using sensitive Droplet Digital PCR 	<ul style="list-style-type: none"> Achieve absolute quantification of residual host DNA using ddPCR Residual DNA Quantification Kits. The sensitivity of Droplet Digital PCR ensures adherence to the U.S. FDA guideline of <100 pg host DNA per dose 	<ul style="list-style-type: none"> Reduce false positives with the VeriCheck ddPCR Mycoplasma Detection Kit  <ul style="list-style-type: none"> Learn how to transition to Droplet Digital PCR from qPCR for Mycoplasma testing 	<ul style="list-style-type: none"> Verify gene expression for anti-CD19 CAR-T cells using the CAR-T CD19 Monitoring Assay  <ul style="list-style-type: none"> Click to read the paper: Insights on Droplet Digital PCR-Based Cellular Kinetics and Biodistribution Assay Support for CAR-T Cell Therapy 	

ddPCR Software

Bio-Rad ddPCR Systems and Software meet the needs of GMP manufacturing and QC environments, complying with the FDA's Title 21 Code of Federal Regulations Part 11 for electronic documentation and signatures. QX Software is a family of powerful software packages for acquiring and analyzing your ddPCR data. When connected to a ddPCR System, QX Software provides all the necessary functionality to create, run, and analyze experiments.

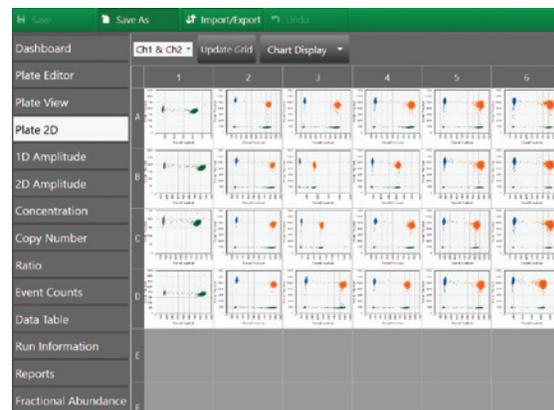
With QX Software, you can:

- Analyze your data files in a variety of charts and tables in the analysis module
- Create customized templates for both reports and plates enabling simple standardization of reporting and data acquisition
- View system and experiment audit logs
- Produce an audit log report on old and new data values after reprocessing a file

Bio-Rad voluntarily complies with International Organization for Standardization (ISO) 13485. This standard has additional requirements beyond ISO 9001, including product-specific demands and more stringent documentation requirements.

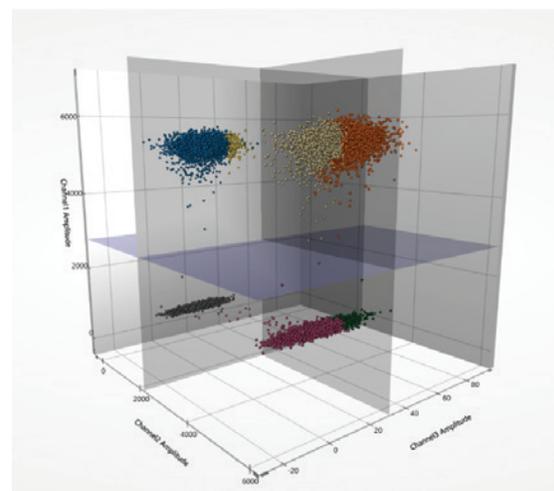
Visit bio-rad.com/QXSoftware to learn more.

Plate 2D Amplitude Chart



QX Software allows you to visualize any combination of channels in 2-D plots, side-by-side on the screen or in a 96-well plate layout.

3D Amplitude Chart



After selecting a well in the toolbar, the 3-D amplitude display illustrates three targets that you can select in a single chart.

ddPCR Application Support and Services

Bio-Rad has the experience and dedicated tools to support the development, analysis, and manufacturing of your cutting-edge cell and gene therapies.

Applications Support

Our dedicated field applications scientists leverage an unparalleled breadth of skills to:

- Provide training and assistance with data analysis, troubleshooting, and optimization
- Assist customers with experimental design, assay design, and reporting of results

Service

With more than 50 years of dependable and experienced service and support to the scientific community, we are here when you need us.

Services include:

- Installation qualification (IQ)
- Operational qualification (OQ)
- Preventative maintenance and operational qualification (PM/OQ)
- Thermal validation

Our service contract plans ensure coverage for routine maintenance and emergency repairs at no additional cost. Plans include:

- Service and repair coverage
- Replacement parts, travel, and labor
- Prioritized response time
- Preventative maintenance for critical components in regulatory environments
- Equipment qualification
- Validation services environments, equipment qualification, and validation services



Droplet Digital PCR Applications Guide

Read in-depth information about setting up experiments for ddPCR applications.

Visit [bio-rad.com/ddPCRAppsGuide](https://www.bio-rad.com/ddPCRAppsGuide) for more information.

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