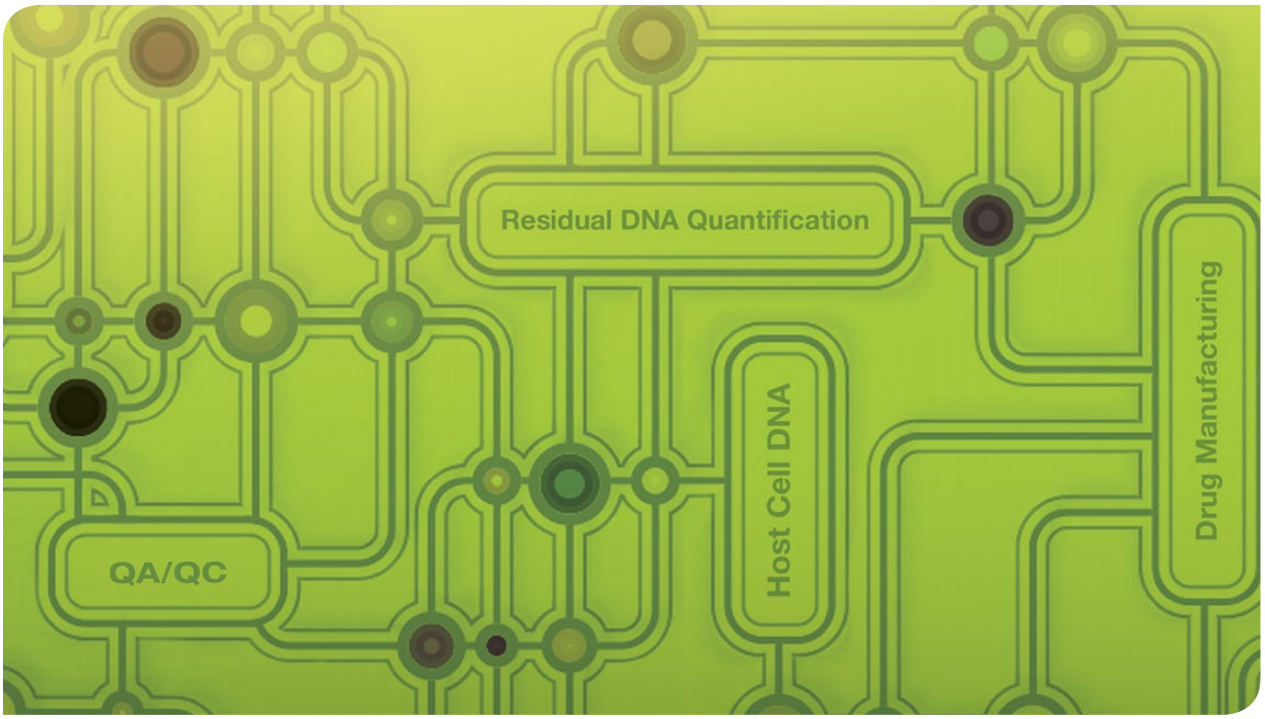

ddPCR Supermix for Residual DNA Quantification

Bio-Rad's ddPCR Supermix for Residual DNA Quantification is a ready-to-use 2x supermix optimized to deliver maximum PCR efficiency, specificity, and sensitivity for direct quantification of residual host cell DNA (HCD) with the QX100™, QX200™, or QX200™ AutoDG™ Droplet Digital PCR System.

When used with these ddPCR Systems, the supermix enables:

- Highly precise and sensitive direct quantification of residual host cell DNA
- Direct quantification without DNA purification steps
- Precise quantification of low levels of *Escherichia coli*, Chinese hamster ovary (CHO), mouse, human, and yeast DNA for residual HCD monitoring
- Precise quantification of low levels of bacterial contamination for environmental monitoring and food testing

Visit **bio-rad.com/web/ddPCRsRDQ** for more information.

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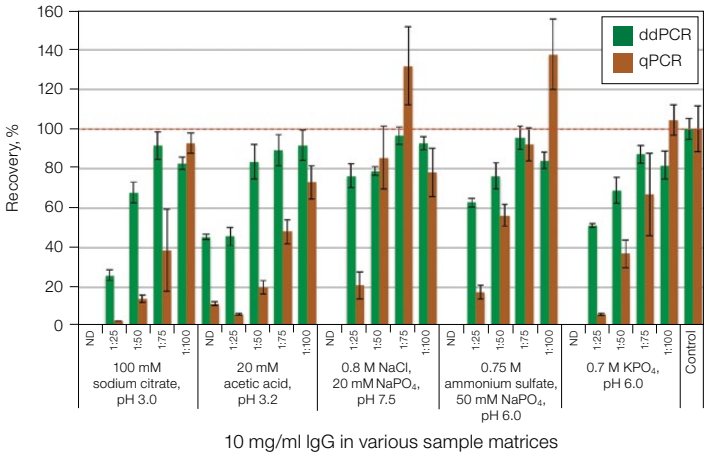
Residual Host Cell DNA Quantification

Many biopharmaceutical products, such as therapeutic proteins and vaccines, are produced by fermentation using either bacterial (for example, *E. coli*) or eukaryotic (for example, CHO) cells in complex media. Manufacturing processes carry through a number of biological molecules derived from the host expression cells, which are present as impurities. One such impurity is host cell DNA, which poses safety concerns and must not exceed established guideline levels from regulatory agencies such as the U.S. Food and Drug Administration and the World Health Organization.

Close monitoring of residual HCD levels throughout the production process is important to control and ensure quality and safety of the final drug product. Quantitative PCR (qPCR) is currently the most commonly used technique to monitor residual HCD, but poses challenges due to inhibition from complex sample matrices. A DNA extraction step is often required before qPCR to remove PCR inhibitors from the sample, but this step can impact recovery of DNA from the sample and lead to inaccurate results.



Precise HCD Quantification without DNA Purification

Bio-Rad's Droplet Digital PCR solution, including the ddPCR Supermix for Residual DNA Quantification, provides a highly precise and sensitive method for residual HCD quantification, without DNA purification. Each reaction becomes less susceptible to inhibition because of the inherent sample partitioning and cycling to end-point features of ddPCR technology. This eliminates the need for DNA extraction or purification. Droplet Digital PCR is also unaffected by PCR efficiency bias and can deliver accurate quantification, even when some level of PCR interference is present (Figure 1). By eliminating the need for DNA extraction, Droplet Digital PCR provides a solution for direct quantification of residual host cell DNA without compromising accuracy, sensitivity, or precision.

Fig. 1. Comparison of ddPCR and qPCR solutions. CHO DNA (100 fg) was spiked into 0-, 25-, 50-, and 100-fold dilutions of different process matrices and directly analyzed using ddPCR and qPCR systems. Data were normalized to a control, CHO DNA in 1x Tris-EDTA buffer, pH 8.0, and reported as percentage recovery. Direct analysis of samples in complex matrices can be achieved with ddPCR analysis, and good recovery of CHO DNA requires less dilution than with qPCR analysis. ddPCR results were also less variable than qPCR. ND, no dilution.

The Entire Droplet Digital PCR Solution

1 ddPCR Supermix for Residual DNA Quantification

2 ddPCR Consumables

3 Automated Droplet Generator

Strict Quality Control

Each manufactured lot of Bio-Rad's ddPCR Supermix for Residual DNA Quantification passes strict quality control for detectable *E. coli*, CHO, mouse, human, and yeast DNA, and is tested for detectable RNase and DNase activity. The supermix is compatible with uracil N-glycosylase (UNG) decontamination methods for additional process control.

Droplet Digital PCR delivers direct detection of *E. coli* and CHO DNA with high precision and femtogram-level sensitivity in complex sample matrices commonly found in biopharmaceutical processing (Figure 2).

Because of Bio-Rad's strict quality control for detectable *E. coli*, the ddPCR Supermix for Residual DNA Quantification is the ideal supermix for low-level *E. coli* detection with Bio-Rad's ddPCR Systems for environmental monitoring and food testing (Figure 2A).

Droplet Digital PCR Workflow

Paired with the QX200 AutoDG ddPCR System, the ddPCR Supermix for Residual DNA Quantification permits streamlined and precise high-throughput quantification of HCD throughout the pharmaceutical production process.

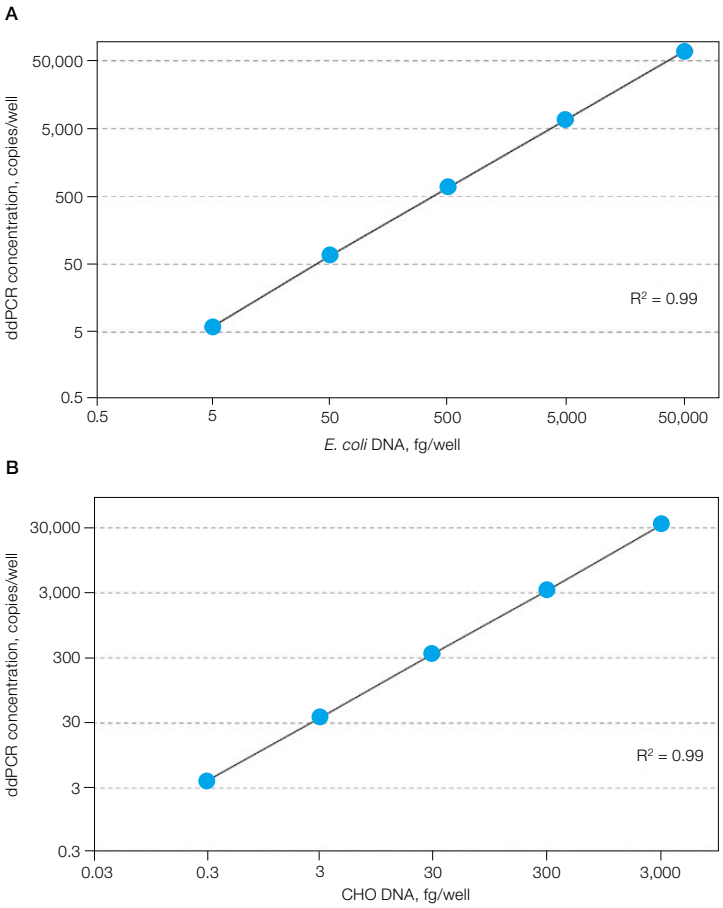


Fig. 2. Sensitivity and precision with Droplet Digital PCR. The sensitivity and precision of a ddPCR solution is observed in **A**, the titration of *E. coli* DNA from 5 fg to 50 pg, and **B**, the titration of CHO DNA from 0.3 fg to 3 pg. Both plots demonstrate good linearity of detection with Droplet Digital PCR.

Ordering Information

Catalog #	Description
1864037	**ddPCR Supermix for Residual DNA Quantification**, 2 ml (2 x 1 ml), 200 x 20 µl reactions, 2x supermix
1864038	**ddPCR Supermix for Residual DNA Quantification**, 5 ml (5 x 1 ml), 500 x 20 µl reactions, 2x supermix
1864039	**ddPCR Supermix for Residual DNA Quantification**, 25 ml (5 x 5 ml), 2,500 x 20 µl reactions, 2x supermix
1864040	**ddPCR Supermix for Residual DNA Quantification**, 50 ml (10 x 5 ml), 5,000 x 20 µl reactions, 2x supermix

Products in the Workflow

QX200 AutoDG Droplet Digital PCR System and Consumables

1864100	**QX200 AutoDG Droplet Digital PCR System**, includes Automated Droplet Generator, QX200 Droplet Reader, laptop computer, QuantaSoft Software
1864101	**Automated Droplet Generator**, includes Automated Droplet Generator, power cord, accessories
1864003	**QX200 Droplet Reader**, includes droplet reader, plate holders, USB cable, power cord
1864108	**DG32™ Automated Droplet Generator Cartridges**, pkg of 30, enough for 10 x 96-well ddPCR Plates
1864109	**DG32 Automated Droplet Generator Cartridges**, pkg of 60, enough for 20 x 96-well ddPCR Plates
1864110	**Automated Droplet Generation Oil for Probes**, 140 ml, enough for 20 x 96-well ddPCR Plates
1864120	**Pipet Tips for Automated Droplet Generator**, pkg of 20, enough for 10 x 96-well ddPCR Plates
1864121	**Pipet Tips for Automated Droplet Generator**, pkg of 40, enough for 20 x 96-well ddPCR Plates
1864125	**Pipet Tip Waste Bins for Automated Droplet Generator**, pkg of 10, enough for 10 x 96-well plates
1863004	**ddPCR Droplet Reader Oil**, 2 L (2 x 1 L)

QX200 Droplet Digital PCR System and Consumables

1864001	**QX200 Droplet Digital PCR System**, includes QX200 Droplet Generator, QX200 Droplet Reader, laptop computer, QuantaSoft Software
1864002	**QX200 Droplet Generator**, includes droplet generator, 1 pkg of 24 DG8™ Cartridges, 1 pkg of 24 DG8 Gaskets, 2 cartridge holders, power cord
1864003	**QX200 Droplet Reader**, includes droplet reader, plate holders, USB cable, power cord
1864007	**Droplet Generator Cartridges and Gaskets**, includes 5 pkg of 24 DG8 Cartridges, 5 pkg of 24 DG8 Gaskets
1864008	**DG8 Cartridges for QX200/QX100 Droplet Generator**, 1 pkg of 24 cartridges
1863009	**DG8 Gaskets for QX200/QX100 Droplet Generator**, 1 pkg of 24 gaskets
1863051	**DG8 Cartridge Holder**
1863005	**Droplet Generation Oil for Probes**, 10 x 7 ml
1863004	**ddPCR Droplet Reader Oil**, 2 x 1 L

Catalog #	Description

Thermal Cyclers and Plate Sealer

1851196	**C1000 Touch Thermal Cycler with 96-Well Fast Reaction Module**, includes C1000 Touch Thermal Cycler Chassis, 96-well fast reaction module, USB flash drive
1851197	**C1000 Touch Thermal Cycler with 96–Deep Well Reaction Module**, includes C1000 Touch Thermal Cycler Chassis, 96–deep well reaction module, USB flash drive
1814000	**PX1 PCR Plate Sealer**, includes heat sealing instrument, plate support block that holds 96-well and 384-well plates, sealing frame, power cord
1814040	**Pierceable Foil Heat Seal**, pkg of 100

Bio-Rad's thermal cyclers and real-time thermal cyclers are covered by one or more of the following U.S. patents or their foreign counterparts owned by Eppendorf AG: U.S. Patent Numbers 6,767,512 and 7,074,367.

The QX100 or QX200 Droplet Digital PCR System and/or its use is covered by claims of U.S. patents, and/or pending U.S. and non-U.S. patent applications owned by or under license to Bio-Rad Laboratories, Inc. Purchase of the product includes a limited, non-transferable right under such intellectual property for use of the product for internal research purposes only. No rights are granted for diagnostic uses. No rights are granted for use of the product for commercial applications of any kind, including but not limited to manufacturing, quality control, or commercial services, such as contract services or fee for services. Information concerning a license for such uses can be obtained from Bio-Rad Laboratories. It is the responsibility of the purchaser/end user to acquire any additional intellectual property rights that may be required.

The QX200 Droplet Digital PCR System and Automated Droplet Generator are for research use only and are not intended for use in diagnostic procedures.

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