

ddPCR™ CHO Residual DNA Quantification Kit
ddPCR™ *E. coli* Residual DNA Quantification Kit



Residual host cell DNA (HCD) that carries over during the process of manufacturing therapeutic proteins and vaccines poses safety concerns and must not exceed levels established by regulatory agencies such as the U.S. Food and Drug Administration and the World Health Organization. Bio-Rad's ddPCR Residual DNA Quantification Kits are ideal for highly precise quantification of HCD in complex bioprocess intermediates. The kits contain an optimized ddPCR CHO or *E. coli* Residual Quantification Assay and ddPCR Supermix for Residual DNA Quantification. Both assay and supermix are guaranteed free of contaminating DNA.

The Residual DNA Quantification Kits are optimized to enable

- Highly precise, femtogram-level quantification of residual CHO or *E. coli* DNA
- Direct quantification without DNA purification steps
- Compatible with Bio-Rad's QX100™, QX200™, or QX200™ AutoDG™ Droplet Digital PCR Systems

Visit bio-rad.com/web/ddPCR-HCD for more information.



Direct Sample Input: Eliminate DNA Extraction Prior to Residual Host Cell DNA Quantification

Many biopharmaceutical products (biologics, vaccines, etc.) are produced in mammalian or bacterial host cells. DNA levels and matrix conditions vary during the purification process, making residual host cell DNA extraction difficult. Inhibitory substances may also be present, making quantification by qPCR difficult and inaccurate. ddPCR eliminates the need for DNA extraction, as partitioning in ddPCR minimizes the effect of inhibitory substances on the PCR reaction, enabling accurate quantification from complex bioprocess intermediates using direct sample input. Proteinase K and DTT can also be used prior to ddPCR to enable direct input of samples containing up to 5 mg/ml of protein (Figure 1).

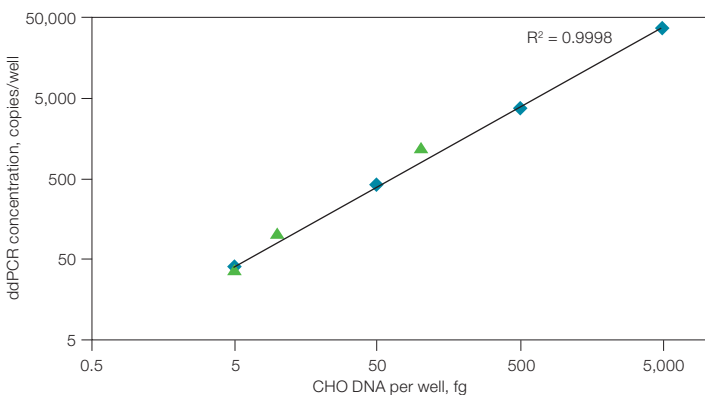


Fig. 1. DNA detection in samples with high IgG levels using Proteinase K pretreatment. CHO DNA was spiked into a sample matrix composed of 100 mg/ml IgG, 3% mannitol, 2% sucrose, 10 mM L-arginine, and 0.01% Tween 20. The sample was then treated with PK and diluted to 100, 10, and 5 fg of CHO DNA prior to ddPCR analysis. CHO standards were also included as controls to determine recovery of the test sample. Full recovery of the CHO DNA was obtained at the three concentrations tested. The data show good linearity, sensitivity, and IgG tolerance. The amount of IgG equivalent in the 100 fg CHO DNA sample is 5 mg/ml. CHO DNA standard (◆); CHO spiked matrix + PK (▲).

Sensitive and Precise HCD Quantification

ddPCR CHO and *E. coli* Residual DNA Quantification Kits enable highly sensitive and precise detection and quantification of host cell DNA without a standard curve. The ddPCR CHO Residual DNA Quantification Kit can reliably detect as little as 1 fg of DNA with a limit of quantification (LOQ) of ≤ 15 fg per 20 μ l reaction and a linear range of 3 fg–3 pg. The ddPCR *E. coli* Residual DNA Quantification Kit can reliably detect as little as 15 fg of DNA with an LOQ of ≤ 30 fg per 20 μ l reaction and a linear range of 30 fg–3 pg (Figure 2).

Free of CHO and *E. coli* Contaminating DNA

The ddPCR CHO and *E. coli* Residual DNA Quantification Assays and ddPCR Residual DNA Quantification Supermixes are guaranteed to be free of contaminating CHO and *E. coli* DNA.

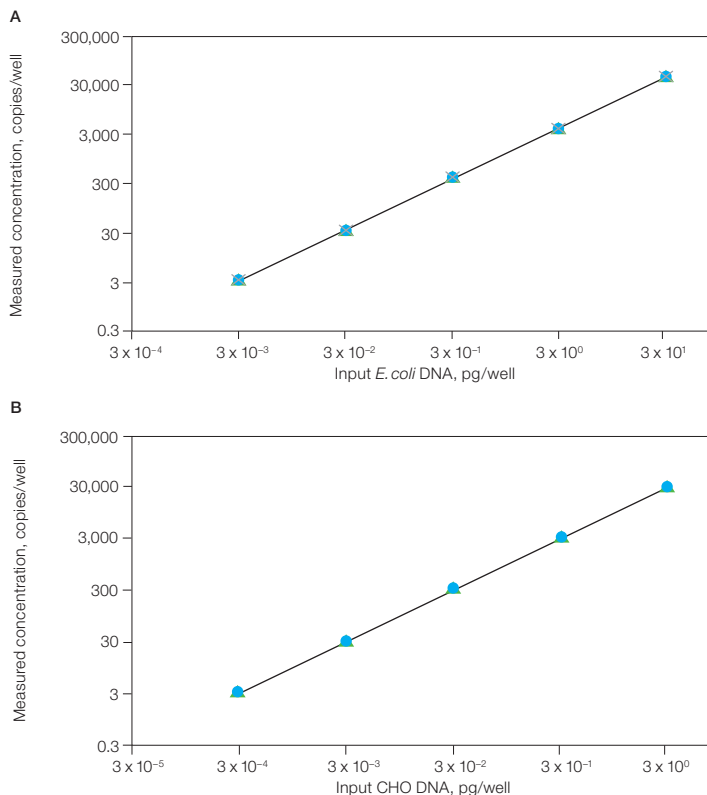


Fig. 2. Titration of *E. coli* and CHO DNA. A, titration of *E. coli* DNA from 3 fg to 30 pg; B, titration of CHO DNA from 0.3 fg to 3 pg. Both plots display highly reproducible results between different lots of assays. Lot 1 (▲); lot 2 (●); lot 3 (×).

Consistent Performance Even with Highly Fragmented DNA

The ddPCR CHO and *E. coli* Residual DNA Quantification Assays yield accurate quantification of results, regardless of the size of the DNA molecules. There is less than 20% variation in concentration calls with intact or fragmented DNA.

Ordering Information

Catalog #	Description
17000032	ddPCR <i>E. coli</i> Residual DNA Quantification Kit
17000031	ddPCR CHO Residual DNA Quantification Kit

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 in the field of digital PCR 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.

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