

## Quantify HEK293 Residual DNA without Extraction



Biotherapeutic products are manufactured in immortalized cell lines, most commonly HEK293. Residual DNA from HEK293 lines can harbor tumorigenic genetic sequences or retroviral sequences that could be transmitted through the biotherapeutic to the human recipients. Accurate quantification of HEK293 DNA is essential to produce a safe and appropriate therapeutic dose. However, the standard methods used for such quantification, like quantitative PCR (qPCR), face challenges due to lack of specificity and reproducibility. The VeriCheck ddPCR HEK293 Res DNA Quant Kit with a novel Droplet Digital PCR (ddPCR) assay has been designed to quantify residual HEK293 DNA in biotherapeutics with high specificity and reproducibility without the need for extraction.

The VeriCheck ddPCR HEK293 Res DNA Quant Kit provides:

**High sensitivity and specificity**

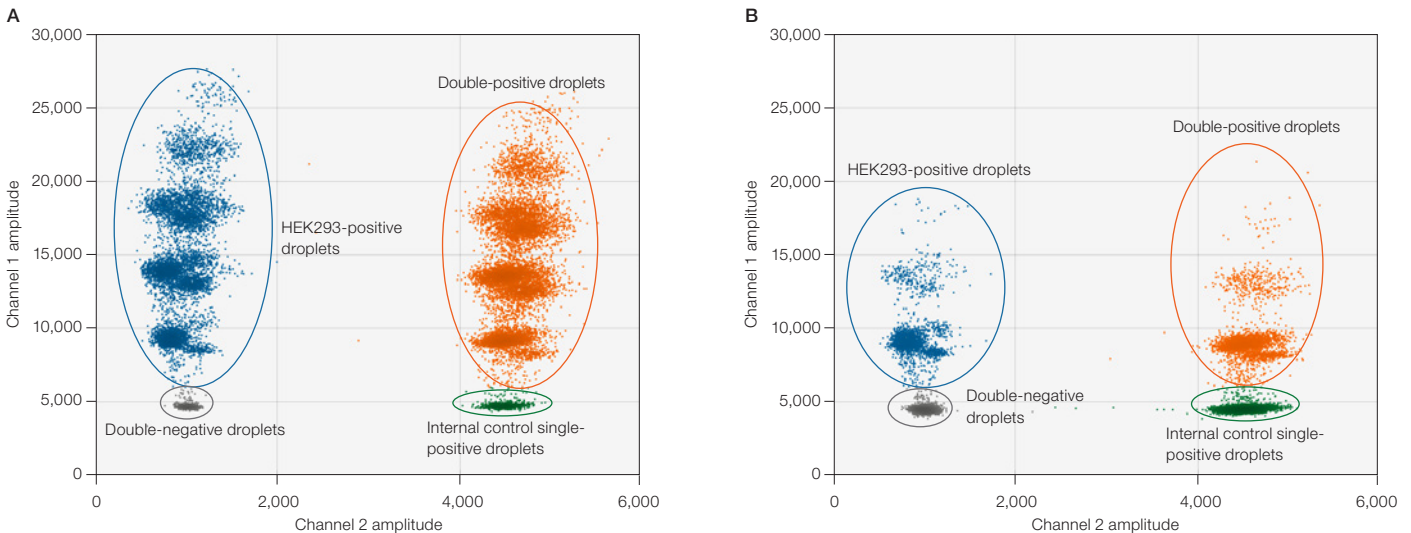
- Limit of detection (LOD) of 0.1 pg/μl (3 wells) and limit of quantification (LOQ) of 1 pg/μl (3 wells)
- Low cross-reactivity and low false-positive rate
- 99.9% specificity to HEK293 DNA when tested against Chinese hamster ovary, *Escherichia coli*, and Vero cells

**Extraction-free, easy-to-use protocol**

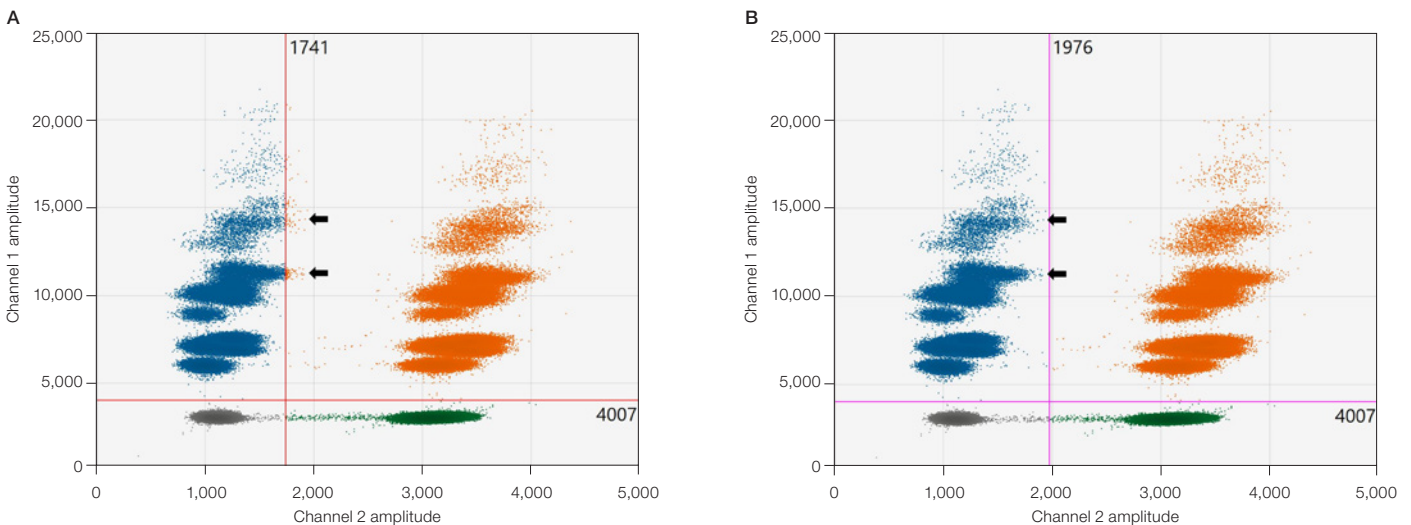
- Broad range of sample types, including in-process samples (cell lysates, cell culture media, sonicated samples, and adeno-associated virus [AAV] vectors) and purified final product (phosphate buffered saline [PBS] with human serum albumin [HSA])

**Positive control-based autothresholding with regulatory compliant software**

- Automated data analysis using in-kit positive control with QX Manager version 1.2/ QX ONE version 1.2 Software
- U.S. FDA 21 CFR Part 11 compliant, offering audit trails with tracked protocol changes



**2-D amplitude plots for the VeriCheck ddPCR HEK293 Res DNA Quant Kit.** Plots show HEK293 signal in channel 1 (FAM) and internal control signal in channel 2 (HEX). The cluster in gray is double-negative for HEK293 and internal control, the blue clusters are positive for HEK293, the green cluster is single-positive for internal control, and the orange clusters are double-positive for HEK293 and internal control. The HEK293 Res DNA Quant assay is a 5-plex assay that detects five targets in the FAM channel. The higher amplitude FAM-positive clusters represent higher occupancy droplets that contain multiple HEK293 target molecules. 2-D amplitude plots show unextracted AAV sample with 25 ng (A) or 2.5 ng (B) residual HEK293 DNA contamination. The internal control is used as an inhibition control for unextracted samples.



**2-D plots showing positive control-based autothresholding.** Positive control-based autothresholding allows for accurate thresholding of an entire plate, simultaneously providing consistent and reproducible results with every run. Accurate thresholds are applied to HEK293 samples with concentrations spanning the ddPCR dynamic range providing consistent, reproducible results. The 2-D plots show the same well before (A) and after (B) positive control-based autothresholding with tilt correction.

Visit [bio-rad.com/ddPCR-VeriCheck-HEK-Quant](https://www.bio-rad.com/ddPCR-VeriCheck-HEK-Quant) for more information.

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