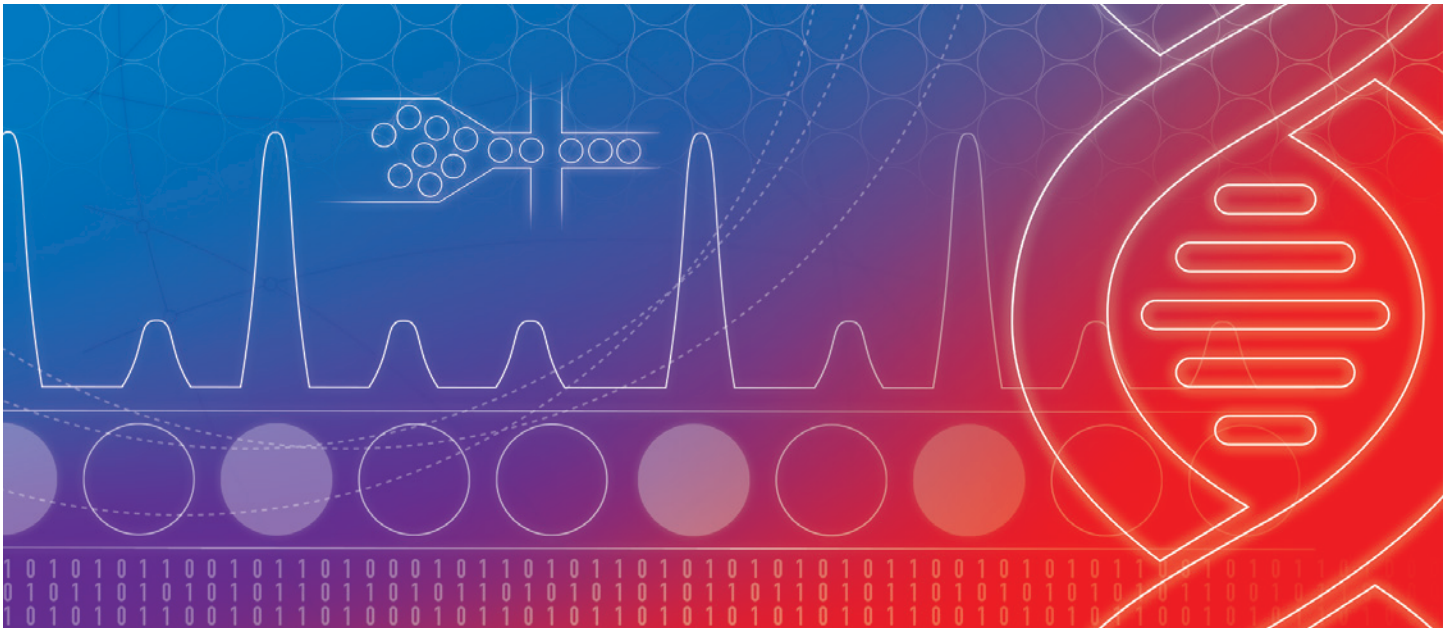

Measure HEK293 Residual DNA Size without a Reference Curve

Human gene therapy products are created in immortalized cell lines, most commonly HEK293. Residual DNA from immortalized cell lines can harbor tumorigenic genetic sequences or retroviral sequences that can cause infection. The U.S. Food and Drug Administration (FDA) recommends that manufacturers degrade any residual DNA to below the size of a functional gene, defined as ~200 base pairs. Manufacturers require an inexpensive, accurate, and reliable way of measuring the size of residual DNA, which Droplet Digital PCR (ddPCR) technology can provide.

The Vericheck ddPCR HEK293 Res DNA Size Kit is the first HEK293-specific sizing solution based on Droplet Digital PCR, designed and validated to meet regulatory guidance requirements and capable of measuring HEK293 size without the use of reference curves.

The Vericheck ddPCR HEK293 Res DNA Size Kit provides:

High specificity and sensitivity

- Low cross-reactivity and low false-positive rate
- >99.99% specificity to HEK293 DNA when tested against Chinese hamster ovary, *Escherichia coli*, Vero, and normal human DNA
- Limit of blank (LOB) of 0 with limit of detection (LOD) of 2 pg/well

Extraction-free protocol without use of standard curves

- Broad range of sample types includes:
  - In-process samples: cell lysates, cell culture media, sonicated samples, and adeno-associated virus vectors
  - Purified final product sample: phosphate buffered saline with human serum albumin using an extraction-free workflow

Visit bio-rad.com/ddPCR-Vericheck-HEK-Size for more information.

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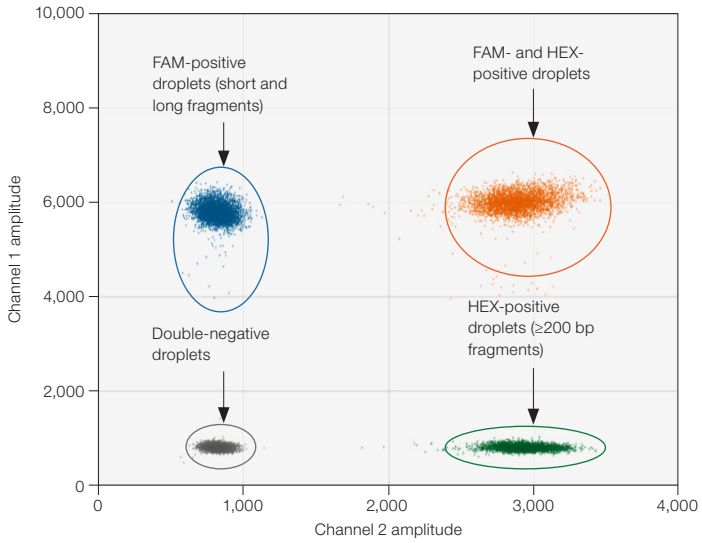
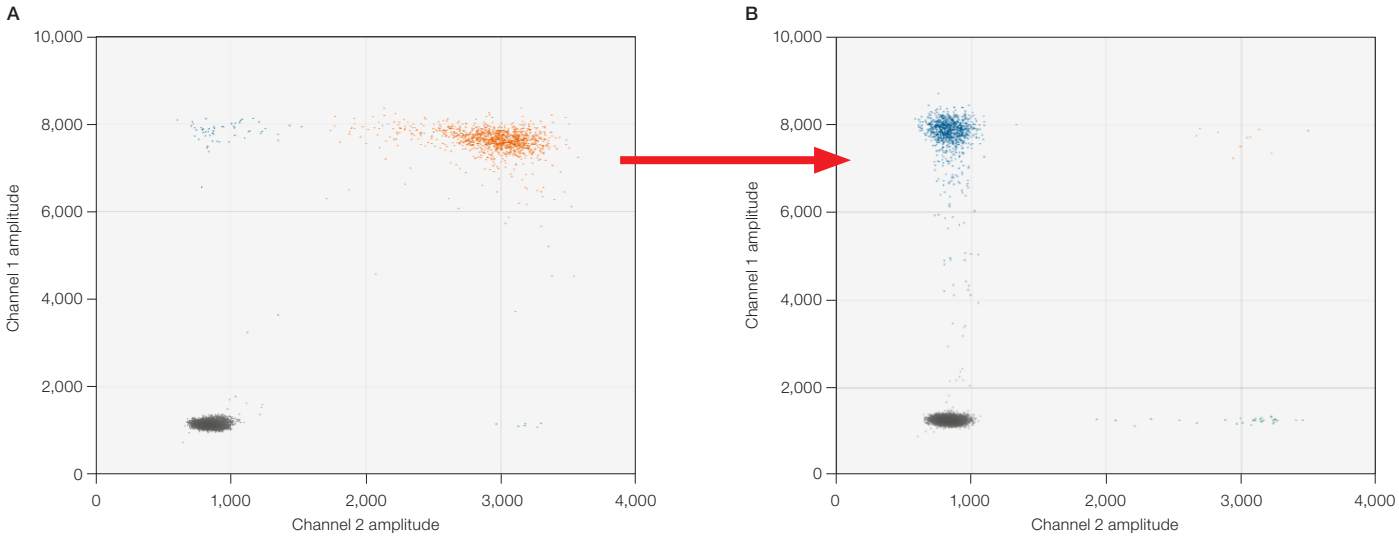
Autothresholding with regulatory compliant software

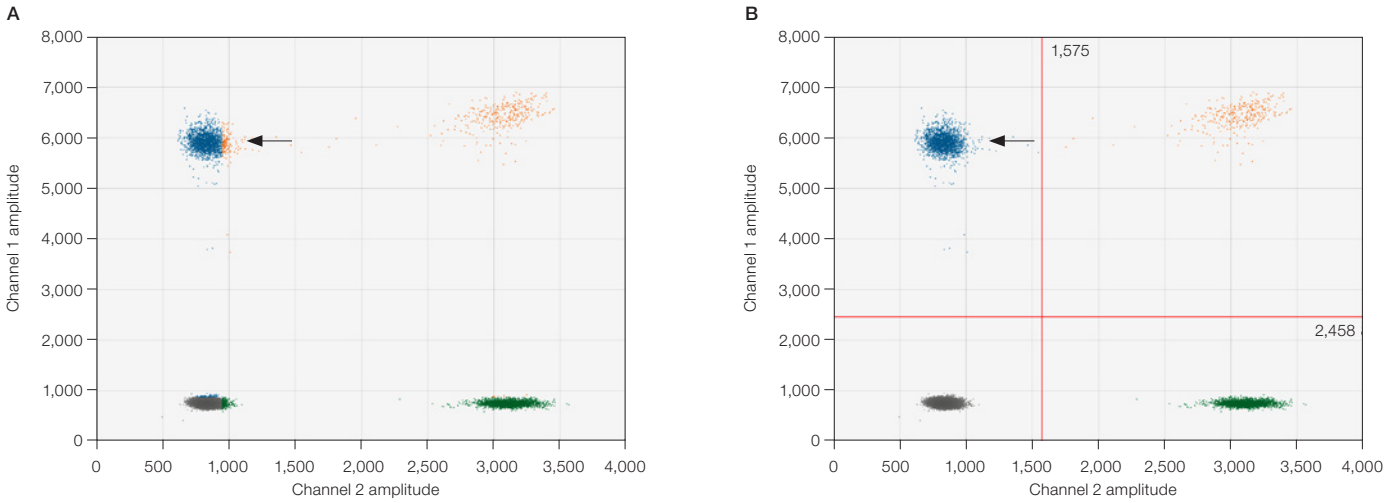
- Provides median size of residual DNA fragments with confidence intervals
- Positive control–based autothresholding with regulatory-compliant 1.2 version of QX Manager or QX ONE Software
- U.S. FDA 21 CFR Part 11 compliant, offering audit trails with tracked protocol changes



2-D amplitude plot for the Vericheck ddPCR HEK293 Res DNA Size Kit. The plot shows HEK293 short and long fragment signals in channel 1 (FAM) and fragments ≥200 base pairs (bp) signal in channel 2 (HEX). The cluster in gray is double-negative for HEK293 DNA, the blue cluster is single-positive for HEK293 short and long fragments, the green cluster is single-positive for fragments ≥200 bp, and the orange cluster is double-positive for both HEK293 DNA sizes.



2-D plots showing fragmentation of HEK293 DNA. (**A**) In unfragmented HEK293 DNA, the two amplicons will have approximately equal signal in the FAM and HEX channels, appearing as double-positives. DNA fragments with a median size of >2,000 bp can be detected. (**B**) As DNA breaks into smaller fragments, the ≥200 bp HEX channel will lose signal more rapidly than the short and long FAM channel, shifting the 2-D plot toward the single-positive FAM cluster with 110 bp median fragment size.



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

Visit **bio-rad.com/ddPCR-Vericheck-HEK-Size** for more information.

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