Droplet Digital PCR

Lentiviruses are commonly used as viral vectors in cell and gene therapy production, delivering and steadily integrating desired genes into the genome of the host cell. However, they may also present health hazards to humans due to integration-mediated transformation and the creation of a RCL that can infect nontarget cells. The U.S. Food and Drug Administration recommends testing sufficient supernatant to ensure a 95% probability of RCL detection if present at a concentration of more than 1 RCL/dose equivalent. While the current regulatory guidelines recommend a cell culture–based method for RCL testing, it is cumbersome and takes 30–45 days from sample to results.

Bio-Rad’s Vericheck ddPCR RCL Kit is fast, cost-effective, specific, and a fully validated solution for lentivirus testing.

Vericheck ddPCR™ Replication Competent Lentivirus (RCL) Kit
A Faster, Quantitative, and Orthogonal Method for Testing RCL

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Visit bio-rad.com/ddPCR-Vericheck-RCL for more information.
Fig. 1. 2-D amplitude plot for the Vericheck ddPCR Replication Competent Lentivirus (RCL) Kit. The plot shows the RCL signal in channel 1 (FAM) and the internal control signal in channel 2 (HEX). The blue cluster is single-positive for RCL DNA, the green cluster is single-positive for internal control DNA, the orange cluster is double-positive for both RCL and internal control DNA, and the gray cluster is double-negative.

The ddPCR RCL Kit Includes:
- ddPCR Supermix for Residual DNA Quantification, 2x supermix
- ddPCR RCL Internal Control
- ddPCR RCL Positive Control
- Nuclease-Free Water (Negative Control)
- ddPCR RCL Assay

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Quick turnaround time
- Get results in <8 hours, compared to 30–45 days for culture-based methods

Qualitative and quantitative results
- Perform automated data analysis with the ability to use prevalidated assay protocol files (APF)

Substantial savings
- Economical alternative to culture-based methods

Specific and sensitive
- 99.9% Specificity
- Limit of detection: 0.87 copies/μl
- ≥95% probability of detection

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