

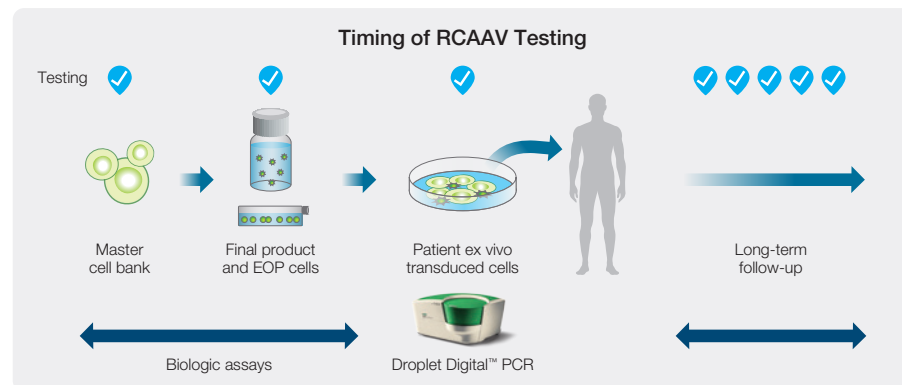
Verichex ddPCR™ Replication Competent AAV (RCAAV) Kit

A Faster, Quantitative, and Orthogonal Method for Testing Replication Competent AAV



Adeno-associated virus (AAV) is commonly used as a viral vector in cell and gene therapy production, but there is a risk of it becoming a replication competent virus (RCV) during the production process, especially in the presence of a helper virus, which can raise safety concerns. The regulatory agency guidelines recommend testing sufficient supernatant to ensure a 95% probability of detection of RCV if present at a concentration of 1 RCV/dose equivalent. While the guidelines recommend a cell culture-based method for RCAAV testing, it is cumbersome and takes 30–45 days from sample to results.

Bio-Rad's Verichex ddPCR RCAAV Kit is a fast, cost-effective, specific, and fully validated solution for AAV testing.



EOP, end of production.

Quick turnaround time



Get results in <8 hours, without the need for extraction

Comprehensive results



Obtain qualitative and quantitative results with the ability to perform automated data analysis

Substantial savings



Economical alternative to culture-based validation methods

Detect all serotypes



Validated with AAV serotypes 1–10

Specific and fast

99% Specificity

Limit of detection: 1.25 copies/μl at a ≥95% probability of detection

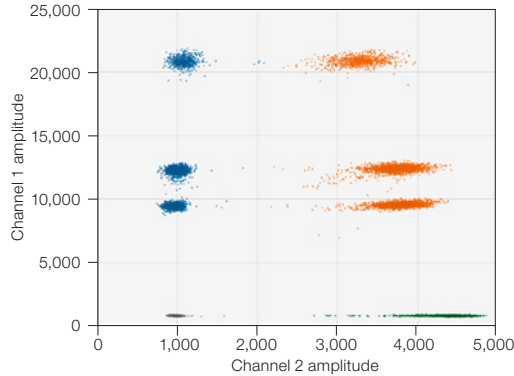


Fig. 1. 2-D amplitude plot for the VeriCheck ddPCR Replication Competent AAV (RCAAV) Kit. The plot shows a positive control well with a RCAAV signal in channel 1 (FAM) and internal control signal in channel 2 (HEX). The blue clusters are positive for RCAAV DNA, the green cluster is single-positive for internal control DNA, the orange clusters are double-positive for RCAAV and internal control DNA, and the gray cluster is double-negative. The RCAAV assay is a multiplex assay that detects AAV serotypes 1–10. Multiple FAM-positive clusters in the positive control represent multiple AAV serotypes. Sample well 2-D plots will contain only one blue single-positive cluster and one orange double-positive cluster.

The ddPCR RCAAV Kit includes:

- ddPCR Supermix for Residual DNA Quantification, 2x supermix
- ddPCR RCAAV Internal Control
- ddPCR RCAAV Positive Control
- Nuclease-Free Water (Negative Control)
- ddPCR RCAAV Assay

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

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