

# **CBER evaluation of porcine circovirus in rotavirus vaccines**

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After reports of porcine circovirus DNA fragments in a rotavirus vaccine identified using a massively parallel sequencing-based virus detection scheme, FDA/CBER undertook a thorough evaluation of potentially implicated vaccines. Rotarix was found to contain full-length, particle-associated PCV-1 genomes that included wild-type sequences, and infectious PCV-1. We did not detect full-length or infectious PCV genomes in Rotateq. Inactivated poliovirus vaccine bulks (produced in a cell bank related to that used for Rotarix) were also negative in a PCV infectivity assay. The use of a massively parallel sequencing-based assay to detect an adventitious agent in a vaccine has led to the suggestion for wider use of these assays in product manufacture and testing. Validation of these assays for use in a regulatory setting presents significant challenges, including the potential for false positives. The PCV example illustrates one approach by which these assays can be paired with other molecular and cell culture approaches to reach scientifically accurate conclusions.