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1. Description

This product is for research use only.

Components	<p>80 µL MACS dPCR COPYcheck Primers (20 µM each)</p> <p>80 µL MACS dPCR COPYcheck Probes (5.5 µM each): Probes are labeled with FAM and Hex dyes.</p> <p>200 µL MACS dPCR COPYcheck Control (10⁴ copies/µL)</p>
Capacity	<p>1.6 nmol of each primer and 0.44 nmol of each probe</p> <p>▲ Note: Numbers of reactions dependent on used protocol. Please refer to the protocol section for further information</p>
Product format	<p>MACS dPCR COPYcheck Primers and Probes are supplied in nuclease-free water.</p> <p>MACS dPCR COPYcheck Control is supplied in a buffered solution of 1 mM TRIS-Cl and 0.1 mM EDTA, at pH 8.0, using nuclease-free water and poly-A-RNA carrier.</p>
Storage	<p>Store protected from light at -20 °C. The expiration date is indicated on the vial label.</p>

1.1 Principle of the MACS dPCR COPYcheck Kit, human

The dPCR vector copy number (VCN) assay is intended to determine the average copies of integrated lentiviral vectors per cell genome after *ex vivo* transduction of human cells. After isolating genomic DNA from the transduced cells, digital PCR determines the copies of the lentiviral gag gene in relation to the human reference gene PTBP2.

The MACS dPCR COPYcheck Kit, human provides specific primers to amplify an amplicon of the lentiviral gag gene and the human reference gene PTBP2. In addition, specific probes comprising fluorescent dyes (FAM/Hex) and quencher moieties are used. During the PCR amplification, the probes bind to the respective target gene and get hydrolyzed by the 5'-3'-exonuclease activity of the PCR polymerase. Thereby, the fluorescent dye separates from the quencher leading to the emission of a fluorescence signal. The digital PCR determines the copy number of the respective gene in the sample.

The MACS dPCR COPYcheck Control is used to control the amplification and quantification of gag and PTBP2. As the human genomic DNA comprises two copies of the PTBP2 gene, the ratio of the copy number of gag and PTBP2 can directly be used to calculate the average copy number of the viral vector in the genomic DNA of the transduced cells.

The primers included in the MACS dPCR COPYcheck Kit, human are only compatible with the lentiviral vectors provided by Lentigen and Miltenyi Biotec.

1.2 Background information

The MACS dPCR COPYcheck Kit, human has been developed for digital PCR (dPCR) systems to determine the vector copy numbers in transduced cells, i.e., the amount of integrated lentiviral vector per transduced cell as characterization of cellular products or as in-process control in production processes using the CliniMACS® Prodigy® or other transduction systems.

2. Protocol

▲ The primers included in the MACS dPCR COPYcheck Kit, human are only compatible with the lentiviral vectors provided by Lentigen and Miltenyi Biotec.

▲ Detailed protocols for the MACS COPYcheck assay using digital PCR systems, e.g. BIO-RAD® QX200™/QX600™/QX ONE Droplet digital PCR™ systems or QIAGEN® QIAcuity® One, Four, or Eight Systems, can be found at www.miltenyibiotec.com/applicationprotocols.

	Number of reactions and volumes
BIO-RAD QX200/QX600/QX ONE Droplet digital PCR systems	80 reactions (1.75 mL reaction volume)
QIAGEN QIAcuity Nanoplate 8.5k	91 reactions (1.1 mL reaction volume)

Table 1: Examples of reaction volumes. Contact Miltenyi Biotec Global Technical Support for non-listed digital PCR (dPCR) instruments .

Refer to www.miltenyibiotec.com for all data sheets and protocols. Miltenyi Biotec provides technical support worldwide. Visit www.miltenyibiotec.com for local Miltenyi Biotec Technical Support contact information.

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