Miltenyi Biotec

MACS® dPCR LENTIcheck Kit (BaEV)
human

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1. Description

This product is for research use only.

Components	**80 µL MACS dPCR LENTIcheck (BaEV) Primers** (20 µM each) **80 µL MACS dPCR LENTIcheck (BaEV) Probe** (5.5 µM)**:** Probe is labeled with FAM dye. **100 µL MACS dPCR LENTIcheck (BaEV) Control** (10^4 copies/µL)
Capacity	1.6 nmol of each primer and 0.44 nmol of the probe ▲ **Note**: Numbers of reactions dependend on used protocol. Please refer to the protocol section for further information.
Product format	MACS dPCR LENTIcheck (BaEV) Primers and Probe are supplied in nuclease-free water. MACS dPCR LENTIcheck (BaEV) Control is supplied in a buffered solution of 10 mM TRIS-Cl and 0.1 mM EDTA, at pH 8.0, using nuclease-free water and poly-A-RNA carrier.
Storage	Store protected from light at +2 to +8 °C. If the reagents are not used within 3 months, store at –20 °C protected from light. When MACS dPCR LENTIcheck (BaEV) Control was stored at –20 °C, reheat at +50 °C for 20 minutes before use. The expiration date is indicated on the vial label.

1.1 Principle of the MACS dPCR LENTIcheck Kit (BaEV), human

The dPCR replication-competent lentivirus (RCL) assay is intended to detect the lentiviral envelope gene sequence (baboon envelope (BaEV) gene) of potential RCLs that might arise, e.g., during unintended recombination of plasmids used in vector production or due to recombination of the viral vector with viral sequences in cells after transduction.

The MACS dPCR LENTIcheck Kit (BaEV), human provides specific primers to amplify an amplicon of the lentiviral envelope BaEV gene sequence. The envelope gene (BaEV) is the most suitable target for detecting RCLs for the usage of vectors that contain this gene, since the sequence must be incorporated to generate a replication competent virus.

A BaEV-specific probe comprising a fluorescent dye (FAM) and quencher moiety is additionally used. During the PCR amplification, the probe binds to the BaEV gene and gets hydrolyzed by the 5′-3′-exonuclease activity of the PCR polymerase. Thereby, the fluorescent dye is separated from the quencher leading to the emission of a fluorescence signal. The number of positive events determined by digital PCR is used to calculate the detected copies of the respective gene in the sample.

The MACS dPCR LENTIcheck (BaEV) Control is used to determine the linearity and sensitivity of the BaEV gene detection. Additional positive and negative controls are used to ensure proper detection of the BaEV gene. No signals should be gained for the viral vector or the transduced cells under investigation.

The primers included in the MACS dPCR LENTIcheck Kit (BaEV), human are intended to be used with the lentiviral vectors provided by Lentigen and Miltenyi Biotec. For information about compatibility with other lentiviral vectors, please contact Miltenyi Biotec Technical Support.

1.2 Background information

During the production of lentiviral vectors as well as in cells transduced with lentiviral vectors, there is the risk of an interplay between the viral vector and viral properties gained from other potentially present viruses or virus genes. Such an interplay might give rise to RCLs, also named replication-competent retroviruses (RCRs). The MACS dPCR LENTIcheck Kit (BaEV), human has been developed to detect the gene encoding for the pseudotyping envelope protein BaEV. The BaEV gene is used to express the envelope protein during the production of lentiviral vectors to enable the packaging of the vector. However, BaEV should not be present in the viral vector. Therefore, the viral vector as well as the transduced cells are intended to be free of BaEV gene. The presence of the BaEV gene can be detected using the MACS dPCR LENTIcheck Kit (BaEV), human. The absence of the BaEV gene in *ex vivo* transduced cells according to the dPCR assay can be used for lot release testing, in particular, when time constraints are present.

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2. Protocol

▲ The primers included in the MACS dPCR LENTIcheck Kit (BaEV), human are intended to be used with the lentiviral vectors provided by Lentigen and Miltenyi Biotec. For information about compatibility with other lentiviral vectors, please contact Miltenyi Biotec Technical Support.

▲ Detailed protocols for the MACS LENTIcheck 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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