

Certificate Of Analysis

Background

KILR CD16 Effector Cells are purified human cytotoxic T lymphocytes stably expressing CD16 (FcγRIIIa; V158 variant), produced in a standardized batch. The cells were developed for antibody-dependent cell-mediated cytotoxicity (ADCC) applications where low lot-to-lot variability is required, such as lot release of therapeutic antibodies.

Product Name	KILR[®] CD16 Effector Cells
Cryovial Label	KILR [®] CD16 Effector Cells
Part #	97-0007
Lot #	21L1801CC
Cell Type	Oligoclonal human cytotoxic T lymphocytes
Receptor	CD16
Species	Human
Variant	V158
Receptor Description	Fc fragment of IgG receptor IIIa (FcγRIIIa; CD16)

Product Information	
Expected Cell Number (millions) per Vial at Thaw	20 ±15%
Fill Volume per Vial (mL)	1
Typical Viability at Thaw (%)	85

Note: recommended minimal recovery time for cells prior to use in assays is 24 hours when handled as described in accompanying KILR[®] CD16 Effector Cell User Manual.

Required Reagents for Thawing and Maintenance of KILR CD16 Effector Cells	
AssayComplete™ Cell Culture Kit-117	Part #: 92-3117G
Recombinant Human IL-2, Cell Culture Grade	Part #: 92-1331

Biosafety Testing	
Assay and Method	Result
Bacteria, yeast, fungi, (Sterility)	Negative
Mycoplasma (qPCR)	Below detection threshold (<10 copies/100 ng of DNA)
HIV1 proviral DNA (qPCR)	Below detection threshold (<10 copies/100 ng of DNA)
HIV2 proviral DNA (qPCR)	Below detection threshold (<10 copies/100 ng of DNA)
HTLV1 proviral DNA (qPCR)	Below detection threshold (<10 copies/100 ng of DNA)
HTLV2 proviral DNA (qPCR)	Below detection threshold (<10 copies/100 ng of DNA)
HBV (qPCR)	Below detection threshold (<10 copies/100 ng of DNA)
HCV (RT-qPCR)	Below detection threshold (<100 copies/120 ng of DNA)
EBV (qPCR)	Below detection threshold (<100 copies/100 ng of DNA)
CMV (qPCR)	Below detection threshold (<10 copies/100 ng of DNA)

Shipping and Storage Information	
Shipping Conditions	Dry ice
Storage Conditions	Store in the vapor phase of liquid nitrogen.
Date of Manufacture	February 2022
Expiration Date	January 2025

Shelf life of at least 3 years has been established for KILR[®] CD16 Effector cells when stored in the vapor phase of liquid nitrogen.

Signature: _____

Reviewed by Grace Dolor
QC Supervisor

Signature: _____

Approved by Neil W. Charter, Ph.D.
Head of Operations