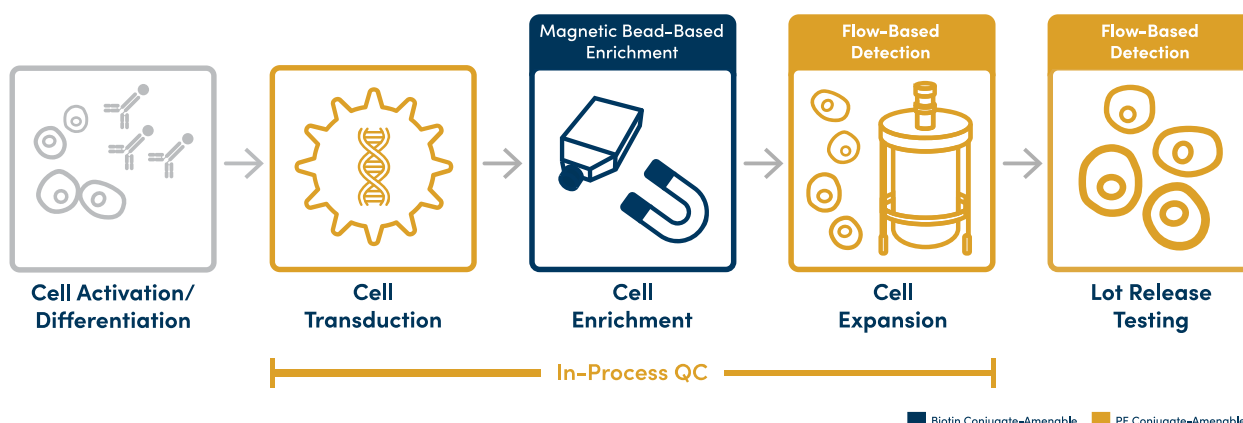




GMP-Grade Recombinant Monoclonal Antibody Conjugates for Cell Therapy Manufacturing & QC



Incorporate robust, flexible CAR Cell Enrichment and Detection into Your Manufacturing and QC Workflows

CST transformed preclinical CAR cell characterization with universal recombinant monoclonal antibodies specific to the ubiquitous Whitlow/218 and G4S linker sequences of scFv-based CARs. This innovation enabled scientists to use a single reagent for a variety of assays without the time or cost of developing anti-idiotype antibodies for every CAR construct.

These trusted antibody conjugates, manufactured to be GMP-grade, are intended to simplify enrichment of G4S linker CAR-positive (CAR+) cells and increase productivity for in-process QC and lot release assays. In addition, production from a clonal master cell bank minimizes lot-to-lot variability.

When preclinical development teams use the same reagents, handoffs can be that much easier as programs advance to later stages.



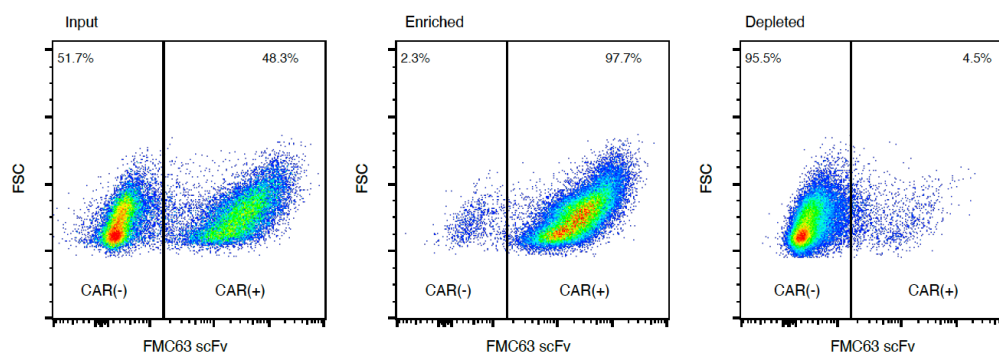
CAR+ Cell Enrichment in Manufacturing



GMP-Grade G4S Linker (E7O2V) Rabbit Monoclonal Antibody (Biotin Conjugate) #22985

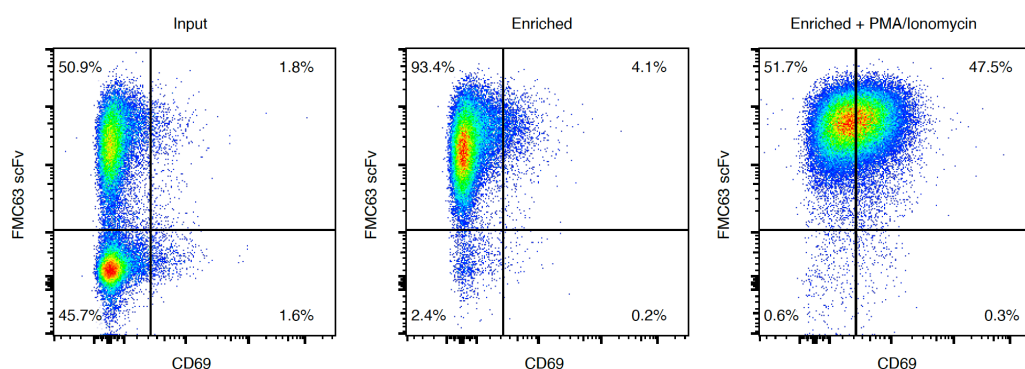
- Enrich CAR+ cells containing multiple G4S repeats with one reagent
- Biotin-conjugated antibodies are amenable to magnetic bead-based CAR-T cell enrichment on cell therapy manufacturing instrumentation
- Standardize percent CAR-positive cells and mitigate issues associated with low transduction efficiencies

Performance of GMP-Grade Biotin Conjugate in Enriching Primary CAR-T Cells



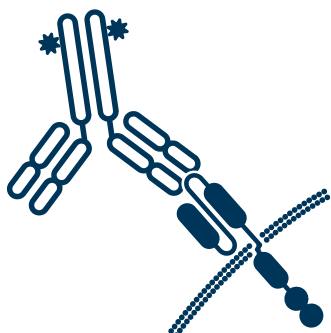
Primary human T cells were transduced to express an anti-CD19 CAR containing an FMC63-based scFv with a G4S linker. G4S Linker (E7O2V) Rabbit mAb (Biotin Conjugate) (GMP-Grade) #22985 enriched CAR+ T cells from a mixed population using the CAR (G4S Linker) Cell Enrichment Kit #48669 protocol. Flow cytometric analysis using an FMC63 scFv (F2Q8G) Rabbit mAb (Alexa Fluor® 488 Conjugate) #41242 showed purity to be >90% with minimal loss of CAR+ cells in the depleted population.

Activation State of Primary CAR-T Cells Following Enrichment With GMP-Grade Biotin Conjugate



Input and 24h post-enrichment cells were co-stained using a FMC63 scFv (F2Q8G) Rabbit mAb (Alexa Fluor® 488 Conjugate) #41242 and T-cell early activation marker CD69. PMA/Iono-treated enriched cells served as a chemically induced positive activation control. Enriching primary human anti-CD19 (FMC63) CAR-T cells with GMP-Grade G4S Linker (E7O2V) Rabbit Monoclonal Antibody (Biotin Conjugate) #22985 does not significantly activate them.

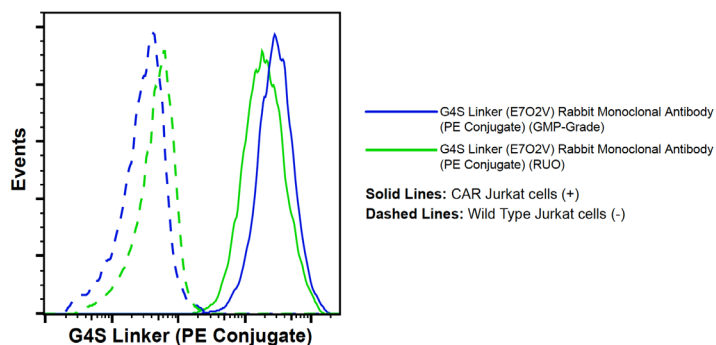
CAR+ Cell Detection for Analytical QC



GMP-Grade G4S Linker (E7O2V) Rabbit Monoclonal Antibody (PE Conjugate) #22996

- Detect CAR+ cells containing multiple G4S repeats with one reagent
- Simplify in-process QC and lot release assays
- PE-conjugated antibodies plug into your existing analytical QC workflows flow cytometry panels
- Amenable to CAR+ cell detection in flow cytometry and FACS-based enrichment

Performance of GMP-Grade PE Conjugate Compared to RUO PE Conjugate in a Flow Cytometry Assay



G4S Linker (E7O2V) Rabbit mAb (PE Conjugate) (GMP-Grade) #22996 was evaluated against RUO #38907 in G4S linker CAR-expressing Jurkat cells. GMP-Grade PE Conjugate #22996 showed higher fluorescence than RUO #38907, even at a lower optimal working concentration.



Seamless Transfer from Pre-Clinical to Clinical

- Achieve smoother handoffs when the same GMP-grade reagents are used in preclinical development as in manufacturing and QC
- Save time qualifying reagents for advanced process development



Reagent Security and Supply Continuity

- The products follow a GMP-compliant process, with required documentation and a controlled chain-of-custody to ensure traceability
- Recombinant monoclonal antibodies produced from a clonal Master Cell Bank ensure lot-to-lot consistency

Translational-Grade Recombinant Monoclonal Antibody Conjugates for Cell Therapy Manufacturing & QC Process Development



CAR+ Cell Enrichment Process Development

G4S Linker (E7O2V) Rabbit Monoclonal Antibody (Biotin Conjugate)
(Translational-Grade) #80462



CAR+ Cell Detection for Analytical QC Process Development

G4S Linker (E7O2V) Rabbit Monoclonal Antibody (PE Conjugate)
(Translational-Grade) #99539

- Ideal for process development; a clear upgrade path to GMP-grade when needed
- Made in the same GMP-certified laboratory as GMP-grade conjugates, using the same processes
- Identical formulation and concentration with equivalent performance to GMP-grade conjugates
- Volume options make ordering the right size easy
- Extended documentation to support audit requirements
- Available globally, with fast shipping

The translational-grade reagents are for Research Use Only (RUO) and not for use in manufacturing or quality control of commercial drug products or diagnostic procedures.



Learn more at:
cst-science.com/CAR-T-GMP

The GMP-grade reagents are not intended for diagnostic use or direct administration into humans or animals. Please read the full Limited Uses statement at cellsignal.com/gmp-limited-uses

The GMP-grade products were manufactured in compliance with regulatory requirements for current Good Manufacturing Practices (cGMP) including 21 C.F.R. Parts 11, 210, 211, 600, and the European Commission Directives 2001/83/EC, as amended, and the European Commission Guidelines of Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 2003/94/EC (Eudralex–Volume1 and 4, Annex 1, Annex 2). Additionally, the products were manufactured to comply with Guidance for Industry Monoclonal Antibodies Used as Reagents in Drug Manufacturing U.S. FDA March 2001, EP chapter 5.2.12, Raw Materials of Biological Origin for the Production of Cell-Based and Gene Therapy Medicinal Products, and USP <1043> Ancillary Materials for Cell, Gene, and Tissue Engineered Products. The final products are stored and maintained in a GMP compliant facility and shipped under Good Distribution Practice (GDP) conditions.

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