

# CAR Cell Therapy

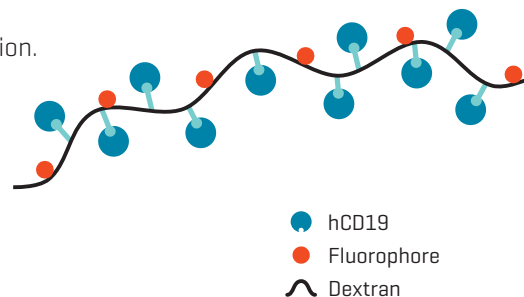
## CAR Dextramer<sup>®</sup> hCD19 for Rapid Detection and Characterization of CD19-Specific CAR-T Cells

CAR Dextramer<sup>®</sup> is a rapid and easy-to-use reagent for CAR cell detection.

This antigen-based reagent serves two purposes:

- demonstrate CAR **presence** on the cell surface
- confirm CAR **binding** to its target antigen.

CAR Dextramer<sup>®</sup> can also be custom-designed for your specific target – ideal for novel CARs and non-ScFv based constructs.



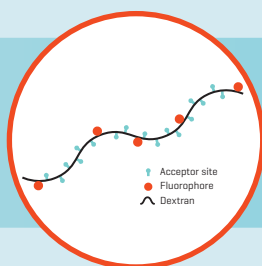
## Interested in Other Targets?

Choose your target antigen



BCMA, CD22, HER2...

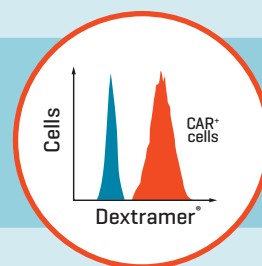
Select reagent(s)



We make the reagent for you



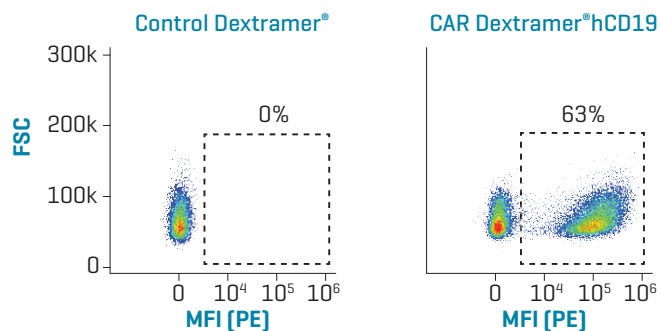
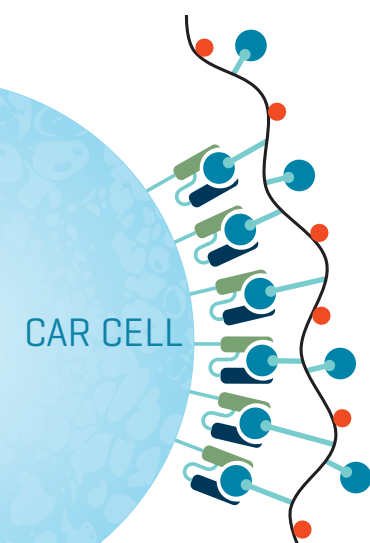
Detect and characterize your CAR cells



Assess % of target-specific Dextramer<sup>®</sup>-positive cells by flow cytometry

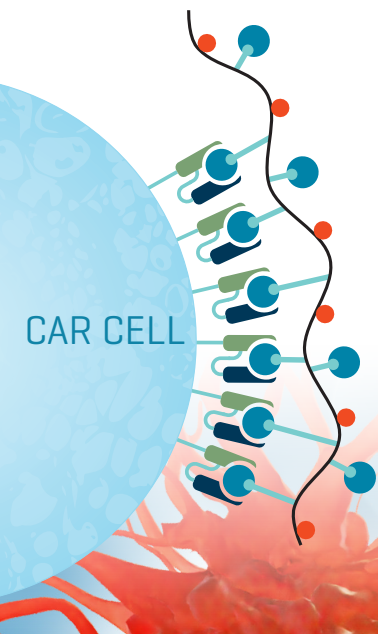
## Streamlined Workflow with CAR Dextramer<sup>®</sup> hCD19

Experience a faster, more efficient process with quick staining and direct detection of CAR cells. CAR Dextramer<sup>®</sup> hCD19 provides precise confirmation of receptor expression and directly verifies the CAR's ability to recognize its target antigen.



Primary human CD19 CAR-T cells stained with PE-labelled CAR Dextramer<sup>®</sup> hCD19. Control Dextramer<sup>®</sup> was used as negative control.

## Enhance CAR Cell Detection with CAR Dextramer<sup>®</sup>



- Optimized Reagent Design:** Backed by over a decade of expertise in immune monitoring, our reagents are meticulously designed for maximum detection performance.
- Enhanced Sensitivity through Multimerization:** Dextramer<sup>®</sup> enables multimerization of the target antigen, enhancing sensitivity in CAR detection, especially when CAR expression is low.
- Reliable Results:** Provides consistent, high-quality results across experiments, ensuring reliable data for research and clinical applications.
- Simplified Staining Protocol:** Our stable, optimized reagents allow for staining at room temperature with minimal wash steps, easing your workflow and minimizing the handling of your cell samples.
- Simultaneous phenotyping:** Room-temperature staining enables the detection of CAR T cells alongside key surface markers, such as CCR7 and CD45, for efficient and comprehensive analysis.

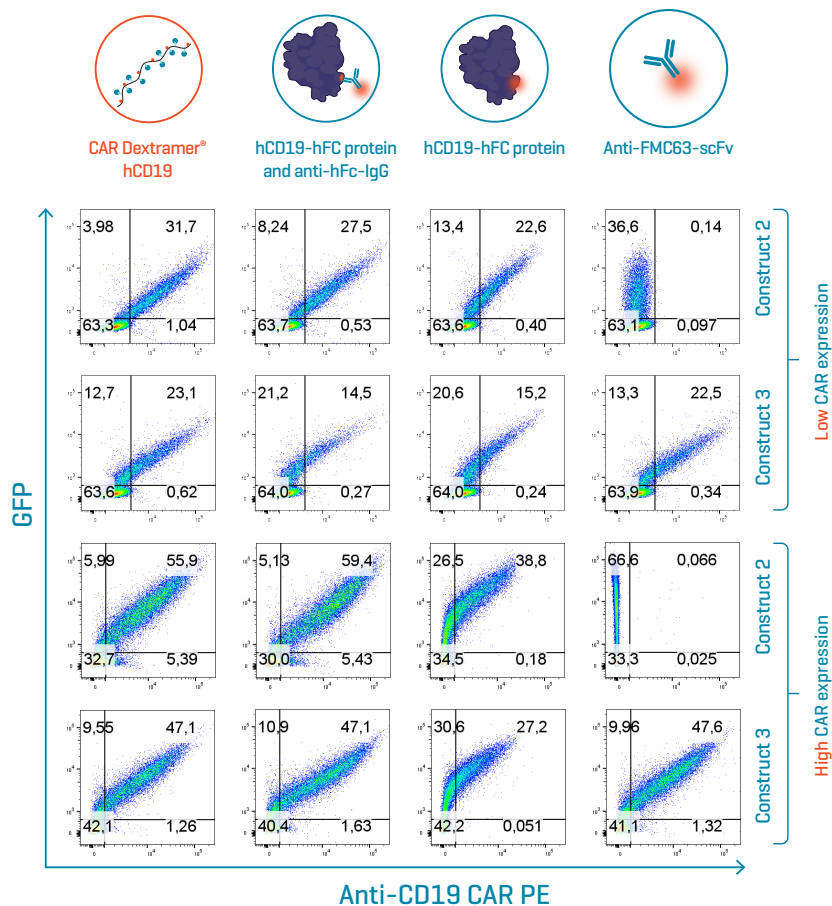
## Superior Detection of CD19 CAR Cells with Low CAR Expression

Our collaborator tested the performance of CAR Dextramer<sup>®</sup> hCD19 in detecting two different anti-CD19 CAR constructs across two CAR-T cell lines [one with low CAR expression and another with high CAR expression].

- Reliable** – CAR Dextramer<sup>®</sup> effectively detects both CD19 CAR constructs with high staining intensity.
- Sensitive** – CAR Dextramer<sup>®</sup> is more effective than other staining reagents in detecting CD19 CAR-T cells with low CAR expression.
- Faster Workflow** – rapid one-step staining protocol and fewer wash steps.

Data kindly provided by collaborator

**BIONTECH**



# FDA Guidance for CAR-T Cell Products

The most recent guidance from the FDA regarding the development of CAR-T cell products includes recommendations for detecting and evaluating the CAR product.

Our products can assist you in adhering to this guidance.



## Manufacturing and Lot Release

*"Control of the manufacturing process and appropriate in process and lot release testing are crucial to ensure CAR-T cell safety, quality and lot-to-lot consistency."*

## Direct Detection of CAR-T cells

*"Direct detection of the CAR to determine the percentage of CAR-positive cells."*

## CAR-T levels in Starting Material

*"If pre-treated with another CAR-therapy, evaluation of the previously administered CAR T cell levels in the cellular starting material may be appropriate."*

## Confirm CAR Binding Specificity

*"Assess the ability of each antigen recognition domain to specifically bind to its target."*

## Comprehensive Characterization of Transduced T Cells

*FDA recommends to examine "uncontrolled proliferation, in vitro and in vivo testing for T cell clonality, karyotypic analysis, TCR repertoire analysis, and specificity for viral antigens through ex vivo stimulation and recognition assays" to document the biological activity of transduced T cells.*

## Identification and Mitigation of On-target/Off-tumor Toxicities

*"Undesired targeting of healthy/normal tissues [on-target/off-tumor] – for example, tissue cross-reactivity studies..."*

## CAR Dextramer® - Direct Detection

Reliable high-quality reagents for CAR cell quantification and lot release testing, or for evaluation of starting material by flow cytometry.

Direct antigen-based detection of CAR cells also verifies CAR identity.

## CAR Dextramer®

Antigen-based detection confirms binding specificity.

## MHC Dextramer®

Available for a wide range of viral specificities for evaluation by flow cytometry.

## dCODE® Technology

Characterize the clonality and TCR repertoire of antigen-specific TCRs through V(D)J sequencing.

## Xynapse™-T

Antigen-specific T cell activation and expansion [substitute for APCs].

## Custom Dextramer® reagents

Antibody multimers enable multivalent binding for sensitive detection of antigen expression in on/off-target tissues.

Supports comprehensive specificity assessment.

## CAR Dextramer® - Easy and Reliable Detection of CAR Cells

### Enables Immune Profiling

Allows concurrent detection of immune markers, e.g. CCR7 and CD45RA

### Sensitive Detection

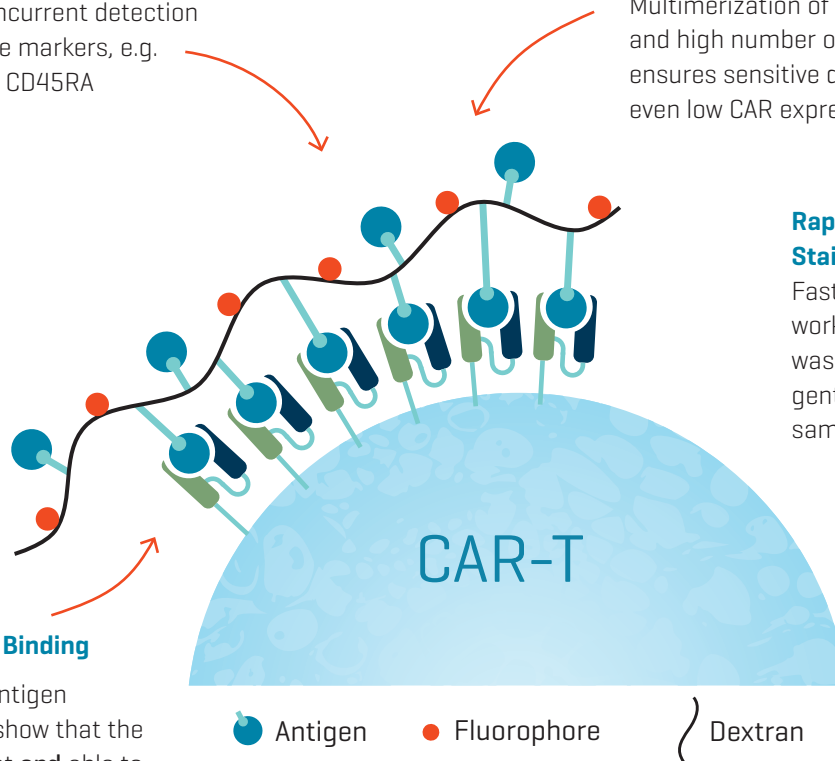
Multimerization of target proteins and high number of fluorochromes ensures sensitive detection of even low CAR expression

### Rapid One-Step Staining Protocol

Fast and easy workflow with minimal washing, ensuring gentle handling of cell samples

### Confirm CAR Binding

Direct CAR-antigen interactions show that the CAR is present **and** able to bind its target antigen.



Catalog Number	Product Name/Description	Test Size	Dye
CT001C	CAR Dextramer®, hCD19	50 tests	PE
DS006	Custom CAR Dextramer® [designed based on your target antigen]	On request	On request

Interested in learning more? Please contact us at [customer@immudex.com](mailto:customer@immudex.com)

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For research use only. Not for use in diagnostic or therapeutic procedures.