

BioSwan Laboratories, Inc.

# Why choose R19M, the best reagent for anti-CD19 CAR-T cell detection

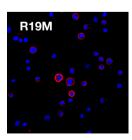
How to improve your detection sensitivity 1000 times more

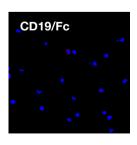
### Background of CAR Expression Evaluation

Evaluating CAR expression is an essential step in production of CAR-T cells. This is often done by flow cytometry by using protein L, anti-Fab antibody, target antigen or anti-idiotype antibody (anti-ID Ab). Among these common choices, anti-ID Ab is widely considered to be the best, because it offers high specificity and minimal background staining. An anti-ID Ab, mouse mab 136.20.1 (B Jena, et al., *PLoS One*, 2013), has been used in anti-CD19 CAR detection extensively by most top labs and Novartis in pre-clinical and clinical studies.

# R19M: A novel tool with higher specificity and sensitivity

R19M (patent pending) is a high affinity rabbit monoclonal antibody specifically binding to the anti-CD19 scFv that was derived from the FMC63. Its robust specificity and sensitivity allows this antibody a perfect tool for flow cytometry and other immunostaining applications.

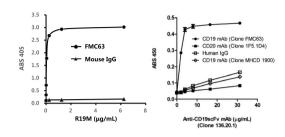




The surface CAR was clearly stained (red fluorescence represents the localization of anti-CD19 CAR on the cell membrane, blue fluorescence represents the nucleus) by R19M (left panel) as compared with antigen CD19/Fc (right panel).

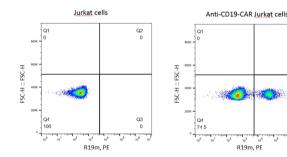
# The strength of R19M

Unique specificity. R19M specifically binds to FMC63 at 0.002  $\mu$ g/ mL, which is 1000 times more sensitive than mAb 136.20.1.



	R19M	136.20.1
Binding started	0.002 μg/mL	2 μg/mL
Binding saturated	0.25 μg/mL	4 μg/mL

**Outstanding accuracy.** Clear clustering of CAR-positive T cells and negative T cells is a prerequisite for accurate detection. R19M clearly defines the anti-CD19 CAR-positive cell population with high affinity, meeting drug quality control and clinical sample testing



Limit of detection 0.01%. Patients treated with CAR-T cells need to monitor the survival of CAR-T cells *in vivo* to determine the efficacy and risk of recurrence. After several months of treatment, the proportion of anti-CD19 CAR-T cells in circulation of patients is mostly below 1%. The sensitivity of detection not only affects the quality of the clinical data, but also affects the feasibility of clinical monitoring. R19M, as a powerful tool for anti-CD19 CAR-T clinical follow-up, pushed the limit of detection to 1: 10,000 (detecting 1 anti-CD19 CAR-T cell in 10,000 PBMC).

25.5

### Current detection reagents

	R19M (Bioswan Lab)	136.20.1 (non-commercial)	CD19/Fc (Other Vendors)
Character	Anti-ID Ab, rabbit	Anti-ID Ab, mouse	Antigen
KD (nM)	0.043	NA	2.95
Limit of detection	0.01%	0.1%	0.5%
Stability (4 °C)	12 months	NA	1 month
Patent	Pending	Issued	No
CAR detection	Yes	Yes	Yes
Clinical monitoring	Long term (> 4 years)	Long term (> 4 years)	Short term (< 3 months)
ADA/Nab study	Yes	Yes	No

ADA/Nab: anti-drug antibodies/neutralizing antibodies. Monitoring of immunogenicity is an important part of the clinical program for CAR-T therapies.

## Related products

Catalog Number	Description	Clone
200120	Anti-Mouse FMC63 scFv mAb (R19M), 100 µg	Rabbit Monoclonal
200106	Anti-Mouse FMC63 scFv mAb (R19M), PE, 100 Tests	Rabbit Monoclonal
500014	Biotin Rabbit Anti-Mouse FMC63 scFv, 100 Tests	Rabbit Polyclonal
500019	Rabbit Anti-Mouse FMC63 scFv, 100 µg	Rabbit Polyclonal
900010	Anti-ID Ab Services: Developing of highly sensitive and specific anti-ID Abs for CAR detection	Rabbit Polyclonal/ Monoclonal

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