

01

薬物動態学的研究試薬 - 抗 FMC63 抗体

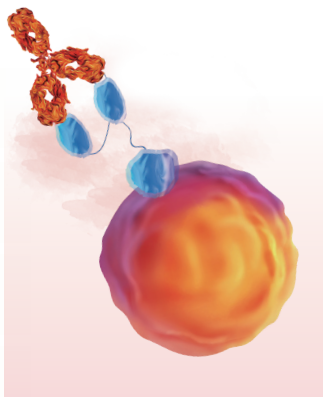
製品の特徴

抗 FMC63 由来 CAR 抗原結合部位を高い親和性で個別に認識可能

CD19 CAR 様細胞で検証済み。遺伝子が導入されていない PBMC には非特異的に結合しません

FITC\PE\APC 蛍光標識済み製品が選択可能

アイソトープコントロールで御社の実験方式開発や結果分析をサポートします



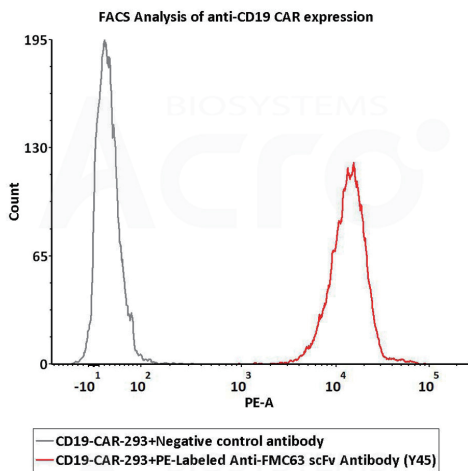
製品情報

| 抗 FMC63 抗体 |                                                                                                                             |                    |
|------------|-----------------------------------------------------------------------------------------------------------------------------|--------------------|
| カタログ番号     | 製品説明                                                                                                                        | サイズ                |
| FM3-AY54P1 | APC-Labeled Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) (Site-specific conjugation)                               | 25tests /200 tests |
| FM3-HPY53  | PE-Labeled Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) (Site-specific conjugation) DMF Filled (Preservative free) | 25tests /200 tests |
| FM3-PY54A2 | PE-Labeled Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) (Site-specific conjugation) DMF Filled (0.03% Proclin)     | 25tests /200 tests |
| FM3-FY45   | FITC-Labeled Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) DMF Filled                                               | 25tests /200 tests |
| FM3-FY45P1 | FITC-Labeled Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) (HEK293)                                                 | 25tests /200 tests |
| FM3-BY54   | Biotinylated Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1, Avitag™ (Y45) DMF Filled                                      | 25tests /200 tests |
| FM3-Y45    | Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) DMF Filled                                                            | 25tests /250 tests |
| FM3-Y45P1  | Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) (HEK293) DMF Filled                                                   | 25tests /250 tests |

| アイソトープコントロール |                                                                              |                    |
|--------------|------------------------------------------------------------------------------|--------------------|
| カタログ番号       | 製品説明                                                                         | サイズ                |
| DNP-PM1      | PE-Labeled Monoclonal Mouse IgG1 Isotype Control (Site-specific conjugation) | 25tests /200 tests |
| DNP-FM1A1    | FITC-Labeled Mouse IgG1 Isotype Control                                      | 25tests /200 tests |
| DNP-BM190    | Biotinylated Mouse IgG1 kappa Isotype Control                                | 25tests /200 tests |
| DNP-M1A1     | Mouse IgG1 kappa Isotype Control                                             | 25tests /250 tests |

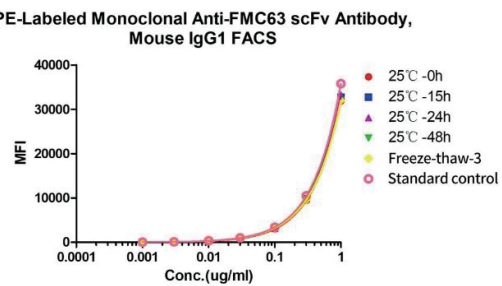
## データ

■ FMC63 由来の抗 CD19 CAR 細胞を検出する際にはバックグラウンド染色を行いません

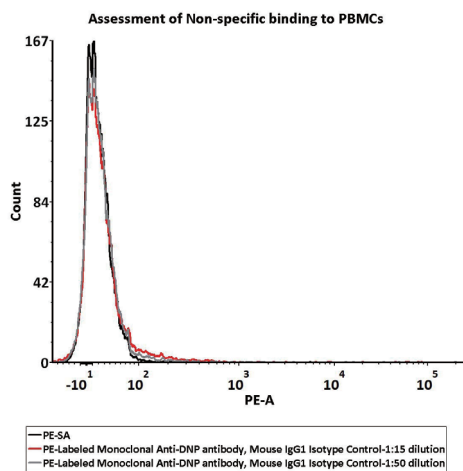


5e5 of the Anti-CD19 CAR-293 cells were stained with 100  $\mu$ L of 1:50 dilution (2  $\mu$ L stock solution in 100  $\mu$ L FACS buffer) of PE-Labeled Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Cat. No. **FM3-HPY53**) and negative control antibody (Cat. No. **DNP-PM1**) respectively, PE signal was used to evaluate the binding activity (QC tested).

■ 安定性の検証

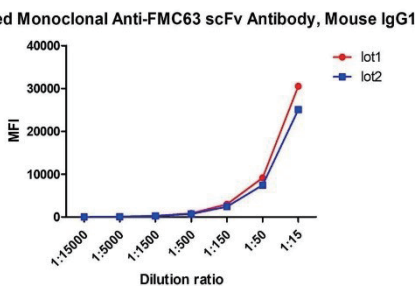


PE-Labeled Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Cat. No. **FM3-HPY53**) at 25°C for 48 hours and freeze-throw cycles are stable without performance reduction.



5e5 of PBMCs were stained with a series of concentrations of PE-Labeled Monoclonal Mouse IgG1 Isotype Control (Cat. No. **DNP-PM1**), and PE signal was used to evaluate the binding activity (QC tested).

■ ロット間の一貫性



Binding activity of two different lots of PE-Labeled Monoclonal Anti FMC63 scFv Antibody, Mouse IgG1(Cat. No. **FM3-HPY53**) against Anti-CD19 CAR-293 cells was evaluated by flow cytometry. The result shows very high batch-to-batch consistency.

02

CD19（FMC63）CAR 免疫原性評価用 ELISA キット

製品の特徴

免疫原性評価アッセイに関する FDA ガイドラインに対応

厳格な品質管理体制、ロット間の一貫性

プロトコルを無償で提供

アッセイの総合的なバリデーション報告書を提出可能

## 製品情報

| カタログ番号   | 製品説明                                           |
|----------|------------------------------------------------|
| RAB-P001 | Anti-CD19 (FMC63) CAR Immunogenicity ELISA Kit |

| 成分のサイズ（96 回用）           | 成分のサイズ（96 回用） |
|-------------------------|---------------|
| High-bind Plate         | 1 plate       |
| Mouse FMC63 scFv        | 25 $\mu$ g    |
| FMC63 ADA Standard      | 100 $\mu$ L   |
| Biotin-Mouse FMC63 scFv | 20 $\mu$ g    |
| Streptavidin-HRP        | 50 $\mu$ L    |
| Coating Buffer          | 12 mL         |
| 10xWashing Buffer       | 50 mL         |
| Blocking Buffer         | 50 mL         |
| Substrate Solution      | 12 mL         |
| Stop Solution           | 7 mL          |

本製品の詳細については QR コードをスキャンしてください

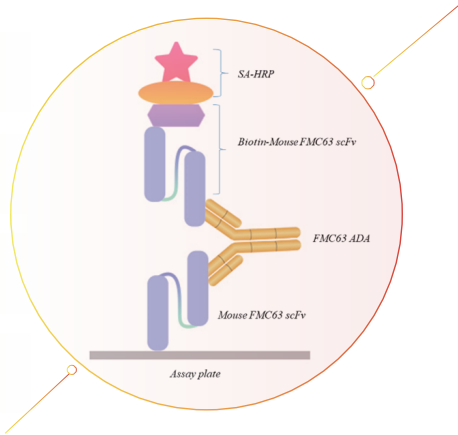


■ 方法論の検証

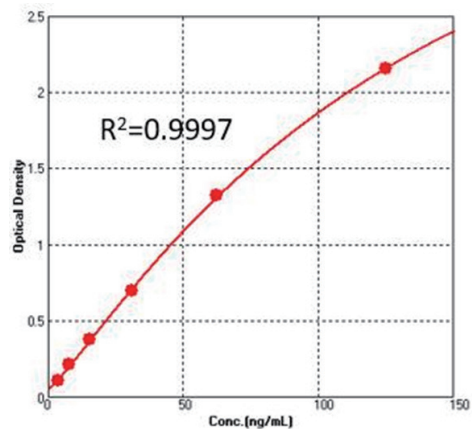
| 基準                              | FDA ガイダンス *                                                                                | 規格                                 | 免疫原性評価アッセイに関する FDA ガイドラインへの対応 |
|---------------------------------|--------------------------------------------------------------------------------------------|------------------------------------|-------------------------------|
| Minimal Required Dilution (MRD) | Ranging between 1:5 to 1:100                                                               | 1:10                               | Yes✔                          |
| Assay Sensitivity               | Less than 100 ng/mL                                                                        | 78 ng/mL                           | Yes✔                          |
| Intra-assay Precision           | CV%≤20%                                                                                    | CV %: 2.4-19%                      | Yes✔                          |
| Inter-assay Precision           | CV%≤20%                                                                                    | CV %: 1.5-5.3%                     | Yes✔                          |
| Hook effect                     | Not observable                                                                             | Not observable                     | Yes✔                          |
| Assay Cut-point                 | Establishment of cut-point with at least 5% false-positive rate with 90% confidence level. | Screening Assay Cut-Point: 0.076** | Yes✔                          |

■ 4 ステップブリッジングアッセイ ELISA 法

- ▶ コーティング：培養用プレートはマウス FMC63 scFv でコーティング済み。
- ▶ サンプル / 被験物質添加：血清または標準サンプル。
- ▶ ビオチン標識済み抗体：ビオチン標識済みマウス FMC63 scFv を添加。
- ▶ 基質の反応：ストレプトアビジン -HRP を添加後、TMB やその他比色分析用 HRP 基質を添加。



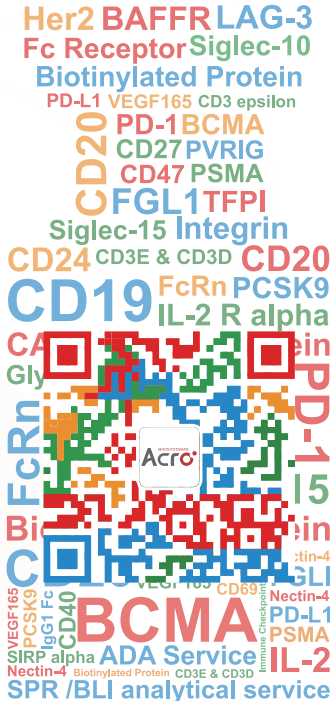
データ



Detection of FMC63 ADA titer by bridging-ELISA Assay. Immobilized Mouse FMC63 scFv can bind FMC63 ADA in 1:10 human serum, and then add Biotin-Mouse FMC63 scFv. Detection was performed using HRP-conjugated streptavidin with sensitivity of 78 ng/mL (QC tested).

FMC63 対応のその他の製品

| アッセイの種類            | カタログ番号      | 種      | 説明                                                                                                         |
|--------------------|-------------|--------|------------------------------------------------------------------------------------------------------------|
| ADA Assay          | FM3-S93     | Rabbit | Rabbit Anti-Mouse FMC63 scFv Polyclonal Antibody (recommended for ADA assay) (MALS verified)               |
|                    | CD9-M52Hb   | Mouse  | FMC63 scFv, His Tag (SPR verified)                                                                         |
|                    | CD9-BV4324b | Mouse  | Biotinylated Anti-CD19 scFv, Fc, Avitag™ (FMC63) (MALS verified)                                           |
| Neutralizing Assay | FM3-Y45A1   | Mouse  | Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) (Carrier-free) (recommended for ADA assay) DMF Filed |



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