

# The Eurofins Viracor ExPeCT™ (Expansion and Persistence of CAR T-cells) anti-CD19 (FMC63) CAR T is an intervention tool that allows the Clinical team to directly monitor the effectiveness of the CAR T-cell

For Hematology/Oncology patients the ExPeCT™ anti-CD19 (FMC63) CAR T assay provides interventional data which may provide information on the expansion and persistence of the genetically modified T-cells used as therapeutic treatment for specific lymphomas and leukemias (Chimeric Antigen Receptor T-cell therapy or CAR T). Eurofins Viracor has developed and validated a multiplexed quantitative real-time PCR (qPCR) assay targeting FMC63 for the longitudinal monitoring of CD19-directed CAR T-cell therapy.

Monitoring of CAR-T cell expansion and persistence can provide important insight into therapeutic efficacy, durability of response, potential for relapse and uncontrolled proliferation. The ExPeCT™ assay described here demonstrates excellent sensitivity, specificity, precision, and accuracy, providing a reliable means of longitudinal monitoring anti-CD19 CAR-T cell expansion and/or persistence in patients receiving any of the current approved therapies (targeting the FMC63 region).



Unlike B-cell apheresis the ExPeCT™ assay is a direct measurement of the quantity of circulating CAR T-cells and serves as a quantifiable measure of therapeutic vitality. Importantly, ExPeCT™ assay does not utilize flow-cytometry, which requires live cell testing.

With laboratory results available within 24 hours after the sample is received, physicians are able to take more directed measures to protect against relapse or refraction. Since this is a non-invasive sample collection, longitudinal monitoring of the CAR T-cells are simpler and less traumatizing to the patient.

**“CAR T-cell therapy is a personalized and targeted treatment utilizing specially altered patient T-cells to fight cancer – a “living drug.””**

Michelle Altrich, PhD, HCLD (ABB)  
President, Eurofins Viracor, Lenexa, KS

## FDA-Approved CAR T-Cell Therapies

Generic Name	Brand Name	Target Antigen	Targeted Disease	Patient Population
Tisagenlecleucel	Kymriah	CD19	B-cell acute lymphoblastic leukemia (ALL)	Children and young adults with refractory or relapsed B-cell ALL
			B-cell non-Hodgkin lymphoma (NHL)	Adults with relapsed or refractory B-cell NHL
Axicabtagene	Yescarta	CD19	B-cell non-Hodgkin lymphoma (NHL)	Adults with relapsed or refractory B-cell NHL
			Follicular lymphoma	Adults with relapsed or refractory follicular lymphoma
Brexucabtagene autoleucel	Tecartus	CD19	Mantle cell lymphoma (MCL)	Adults with relapsed or refractory MCL
			B-cell acute lymphoblastic leukemia (ALL)	Adults with relapsed or refractory B-cell ALL
Lisocabtagene maraleucel	Breyanzi	CD19	B-cell non-Hodgkin lymphoma (NHL)	Adults with relapsed or refractory B-cell NHL

**Assay Name:** Chimeric Antigen Receptor (CAR T) CD19-FMC63

**Assay Test Code:** 33285

**CPT Coding:** 80299

**Specimen Requirements:**

- Collect in EDTA tube, do not centrifuge.
- Can be shipped at ambient or frozen temperature. Mon.- Fri.
- Specimens shipped at ambient temperature must be received within 96 hours of collection.
- Volume: 2 mL (min. 0.5 mL)

**TAT:** 24hrs after receipt of specimen

**Testing Platform:** Quantitative PCR

**Values reported as:** CAR vector copies/μg (calculated field) and CAR vector copies/mL

**Assay Range:** 2.072 to 1.392 x 10<sup>7</sup> CAR vector copies/μg DNA and 100.0 to 6.250E+08 CAR vector copies/mL DNA

## Get Fast Accurate Results

Find out more at [euofins-viracor.com](https://euofins-viracor.com)  
or contact us at [info@euofins-viracor.com](mailto:info@euofins-viracor.com)  
or call **800-305-5198**



To learn more  
about CAR T  
ExPeCT scan  
the QR code

## About Viracor

With over 30 years of diagnostic expertise in infectious disease, immunology and allergy testing for immunocompromised and critical patients, Eurofins Viracor is passionate about delivering accurate, timely and actionable results, never losing sight of the connection between the testing it performs and the patients it serves.

Viracor is a subsidiary of Eurofins Scientific (EUFI.PA), a global leader in bio-analytical testing, and one of the world leaders in genomic services. For more information, please visit [euofins.com](https://euofins.com) and [euofins-viracor.com](https://euofins-viracor.com)

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