

The Eurofins Viracor ExPeCT™ (Expansion and Persistence of CAR T-cells) anti-CD19 (FMC63 or obe-cel) CAR T Assay 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 CAR T assays provide 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 allows 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 demonstrate 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 most FDA approved CD19 therapies.



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.

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 refractorion. 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
<u>Obecabtagene autoleucel</u>	Aucatzyl	CD19	B-cell acute lymphoblastic leukemia (ALL)	Adults with relapsed or refractory B-cell ALL

Assay Name:	Test Code	CPT Code
ExPeCT anti-CD19 (FMC63) CAR T-cell	33285	80299
ExPeCT anti-CD19 (obe-cel) CAR T-cell	33566	80299

TAT: 24hrs after receipt of specimen

Testing Platform: Quantitative PCR

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

FMC63 Assay Range:

CAR vector copies/μg DNA: 2.072 to 1.392 × 10⁷ copies/μg DNA
CAR vector copies/mL DNA: 100.0 to 6.250 × 10⁸ copies/mL DNA

Obe-cel Assay Range:

CAR vector copies/μg DNA: 2.997 to 1.828 × 10⁷ copies/μg DNA
CAR vector copies/mL DNA: 125.0 to 6.250 × 10⁸ copies/mL DNA

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)

Get Fast Accurate Results

Find out more at euofins-viracor.com
or contact us at info@euofins-viracor.com
or call **800-305-5198**



To learn more about CAR T ExPeCT scan the QR code.

About Viracor

With over 40 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 and euofins-viracor.com

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