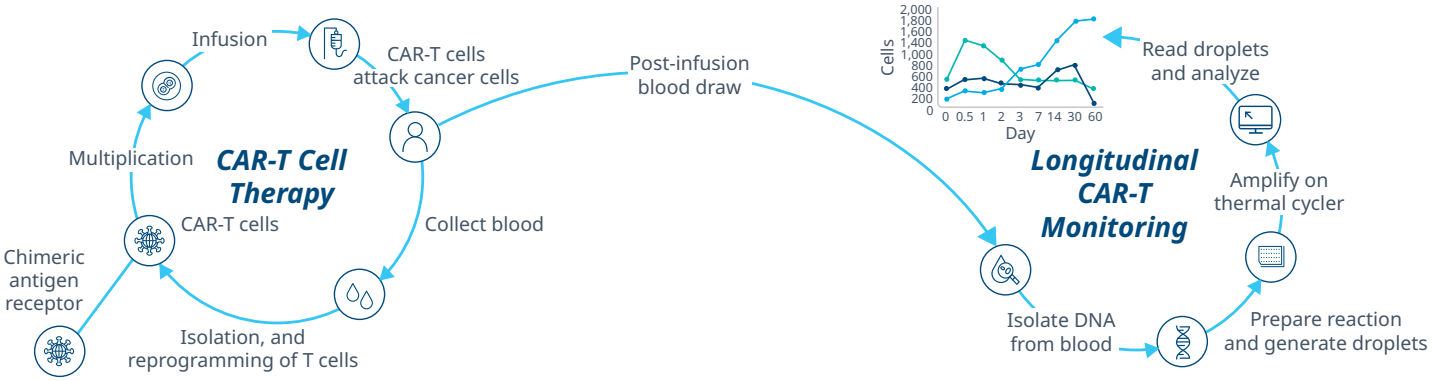
Fact Sheet

CAR Monitoring using Droplet Digital PCR

Custom solutions for monitoring CAR abundance and RCR



CAR-T cell therapy and monitoring using ddPCR. T cells are first harvested and genetically modified with a vector encoding the CAR prior to infusion into the patient as a personalized immunotherapy. To evaluate CAR-T cell abundance post-infusion and correlate with efficacy, biomarker expression, or adverse events, CAR-T monitoring is performed by target amplification of the CAR. Similarly, monitoring for RCR is performed at defined intervals during and after treatment as recombination events could potentially lead to replication competence. This representative workflow is applicable to other cell therapy products such as CAR-NK treatment.

HIGHLIGHTS

Excellent sensitivity and specificity

Customized ddPCR with high sensitivity for detecting Chimeric Antigen Receptors (CAR) and Replication Competent Retrovirus (RCR) designed to meet FDA guidance for limit of quantitation for cell and gene therapy products.

Applicable to various indications

Ideal for use in clinical trials employing CAR cell therapy for the treatment of hematological malignancies, such as acute lymphoblastic leukemia, acute myeloid leukemia, lymphomas, and multiple myeloma.

Empower discovery by leveraging clinical data and biomarkers

Suitable for longitudinal monitoring of cell therapy product and correlating with RNA Seq expression profiles and clinical endpoints such as overall survival, progression-free survival, duration of response, overall response rate.

Flexible logistics

Validated solutions that allow retrospective testing on banked samples or rapid turnaround testing on samples shipped directly from clinical sites during the trial.

Specifications

Assay technology	Droplet Digital PCR
Sample types	2-10 ml whole blood (K2EDTA preferred), PBMCs, BMMCs, bone marrow aspirate
Storage and shipping	Ship overnight according to manufacturers recommendations
Input requirements	~900 ng total DNA as determined by analytical validation
Analytical performance	Developed to meet FDA guidelines of an LOQ <= 50 copies per ug of genomic DNA with 95% confidence
Deliverables	CAR and/or RCR/RCL target and reference copies per reaction and CAR copies per microgram of DNA
Testing locations	RTP, Beijing

IQVIA Laboratories global laboratory network

Global consistency
Harmonized assay testing on **3 continents** for consistent results.

Personalized service
Custom turnaround times for **delivery and analysis.**

Massive data delivery
1.2+ petabytes of genomic data globally in 2024.

Decades of Expertise
Over 20 years in genomics testing.

Industry leader
Leading in genomic testing **since 2001.**

Extensive experience working with the **top 10 pharmaceutical companies.**

IQVIA Genomics has partnered with **> 125 leading/top biotech companies.**

For more information on Cell and Gene Therapy Solutions:
https://labs.iqvia.com/en/central-laboratories/car-t-cell-and-gene-therapy

To learn more about our clinical genomics services, please visit ***https://labs.iqvia.com/genomics-laboratories***

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