

In-depth Monitoring of the Persistence of Allogeneic Cell Therapy (IMPACT)

Cell Therapy Services

Synexa Life Sciences offers a comprehensive portfolio of services and capabilities for cell therapy development, including:

- 30-parameter flow cytometry for functional and phenotypic analysis of the immune system
- Multiplex soluble biomarker analysis using O-Link and MSD
- Transgene quantification
- Immunogenicity assessment
- Tissue analysis including nanostring, IHC and multiplex immunofluorescence (mIF)
- Exosome phenotyping and payload analysis

Our Approach

- **Assay Principle**
The IMPACT-dPCR assay is similar in principle to that used in the field of forensic science, allowing one individual cell to be clearly distinguished from another according to its genetic profile. By applying these principles, the IMPACT-dPCR assay allows clear discernment of allogeneic cells from the native patient cells by quantifying the proportion of allogeneic cells in the patient circulation.
- **Assay Procedure**
The assay involves comprehensive genetic profiling of patient and universal donor cells in order to identify unique alleles which can later be used to distinguish the patients cells from those cells used treatment. Following allele selection, the proportion of donor DNA is quantified using the IMPACT-dPCR assay. This indicates the percentage of allogeneic cells within a patient sample and tracks allogeneic cell persistence over time.
- **Analytical Workflow**
 1. DNA Isolation and Quantification
 2. Genetic profiling
 3. Allele of interest selection – allele present in allogeneic therapy and not recipient
 4. dPCR assay
 5. Allogeneic cell therapy versus donor ratio data analysis

Sample Requirements and Reporting

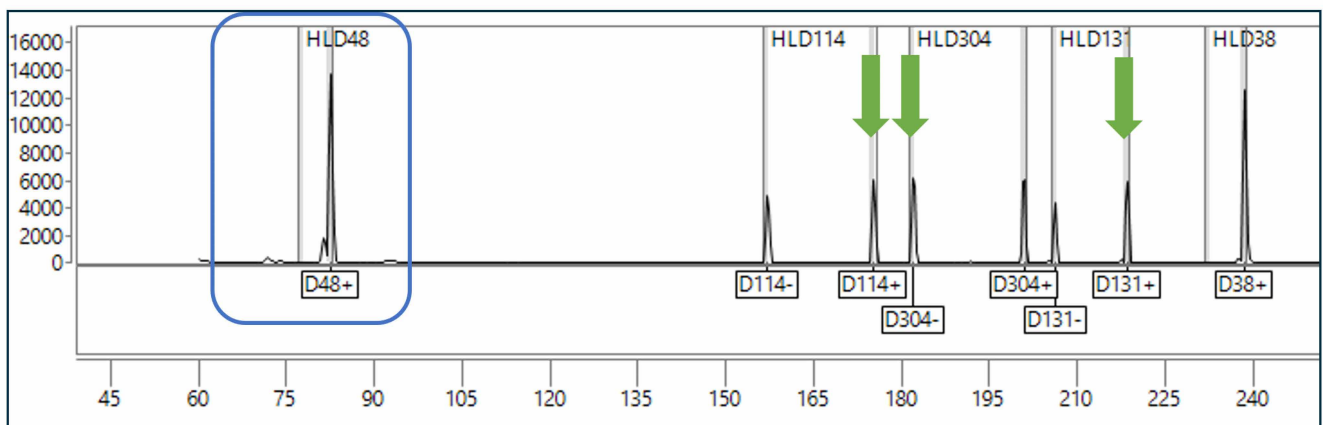
- i. Genetics Screening/Profiling: Isolated DNA input at 5ng/ul minimum
- ii. dPCR analysis: Isolated DNA input at 15ng/ul minimum
- iii. Reporting: Genetics profiling results & dPCR chimeric ratio over time (data and graph illustrating tracking over time)

Discuss your programme with a scientist

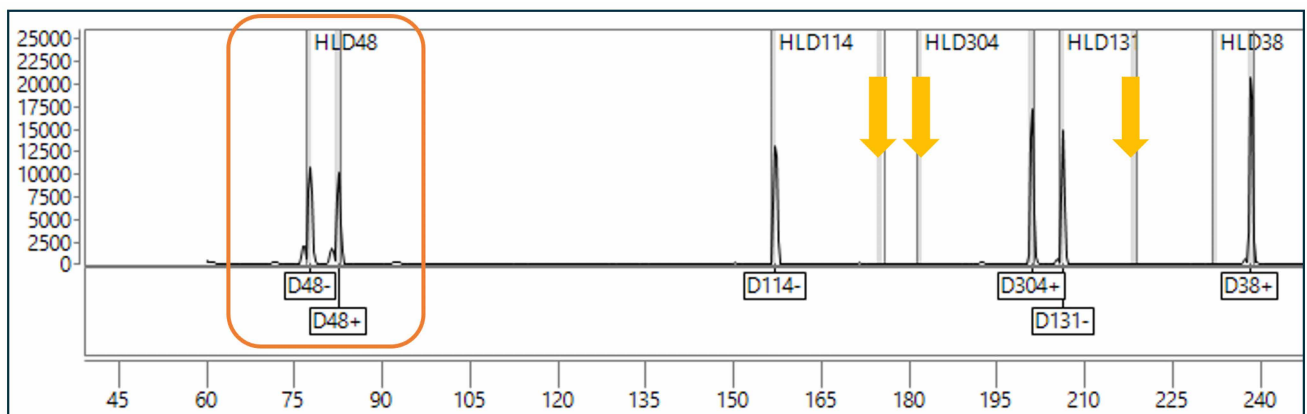
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Email our team at contactus@synexagroup.com to get started.

Case Studies

A: Allogeneic Cell Therapy Donor



B: Patient



The image above illustrates the output of genetic profiling data of two individuals. Multiple Human Locus DIPs (HLD) are screened using fragment analysis. Each individual carries two alleles, one from each parent. The presence of alleles is indicated by peaks. Every individual is either homozygous at an HLD (example in blue) or heterozygous (example in orange). To select an allele of interest, differences between the donor and patient profiles need to be determined. Image A shows an example of an allogeneic cell therapy donor profile with unique alleles indicated by the green arrows (peaks present). Image B shows an example of a patient profile who will be receiving the allogeneic cell therapy treatment that do not possess these alleles (yellow arrows – no peaks).

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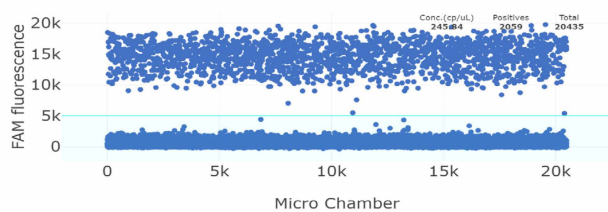


Figure 1. No Chimerism: 100% Allogeneic Donor Cell

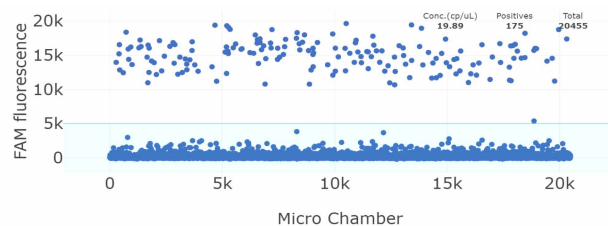


Figure 2. 50% Chimerism: 50% proportion of sample contains allogeneic donor cells

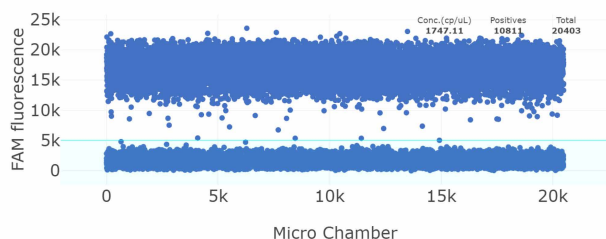


Figure 3. 10% Chimerism: 10% proportion of sample contains allogeneic donor cell

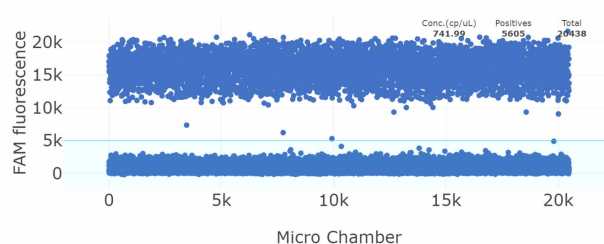


Figure 4. 1% Chimerism: 1% proportion of sample contains allogeneic donor cell

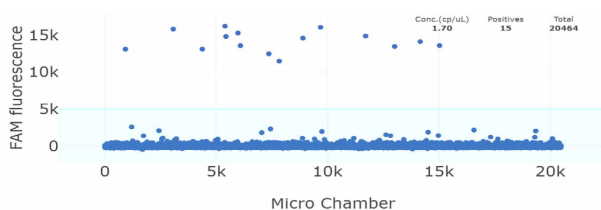


Figure 5. 0.1% Chimerism: 0.1% proportion of sample contains allogeneic donor cells

The images illustrate the dPCR quantification data output of a sample constituting 100%, 50%, 10%, 1% and 0.1% of the donor selected AOI (intra-assay). The alleles present only within the donors' cells are quantified using fluorescently labelled DNA-oligonucleotides targeting the donor alleles specifically. From this data, a DNA proportion calculation (%) can be performed for In-depth monitoring and persistence of allogeneic cell therapies.

The IMPACT method has been validated to detect down to 0.05% (0.02% also assessed but results slightly variable at this level) of allogeneic cells present within a patient sample.

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