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Chimerism testing **Monitoring of engraftment**

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Introduction

We offer rapid and highly sensitive chimerism testing for post-transplant monitoring. Important clinical events in allogeneic bone marrow transplantation such as engraftment, relapse, and the effects of post-transplant therapies can be monitored on a molecular level by detecting genetic differences between recipient and donor. Our test takes advantage of highly polymorphic loci called Short Tandem Repeats (STR). Test results are used to monitor the relative amounts of recipient and donor cells present after transplant.

Enriched cell populations can be used to monitor engraftment in patients following hematopoietic stem cell transplantation.

Testing for lineage specific chimerism for the following cell type is also available:

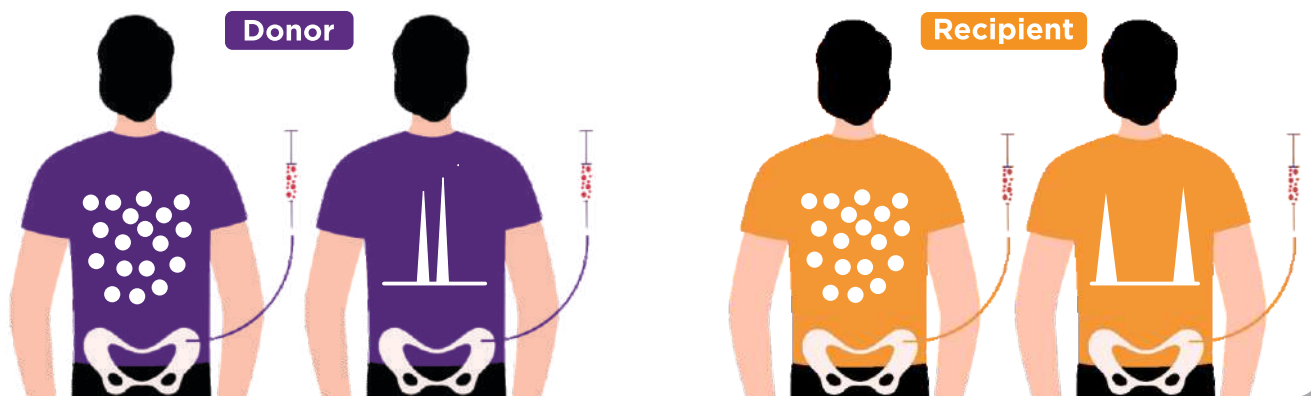
Cell marker : CD3

Cell Subset : T cells

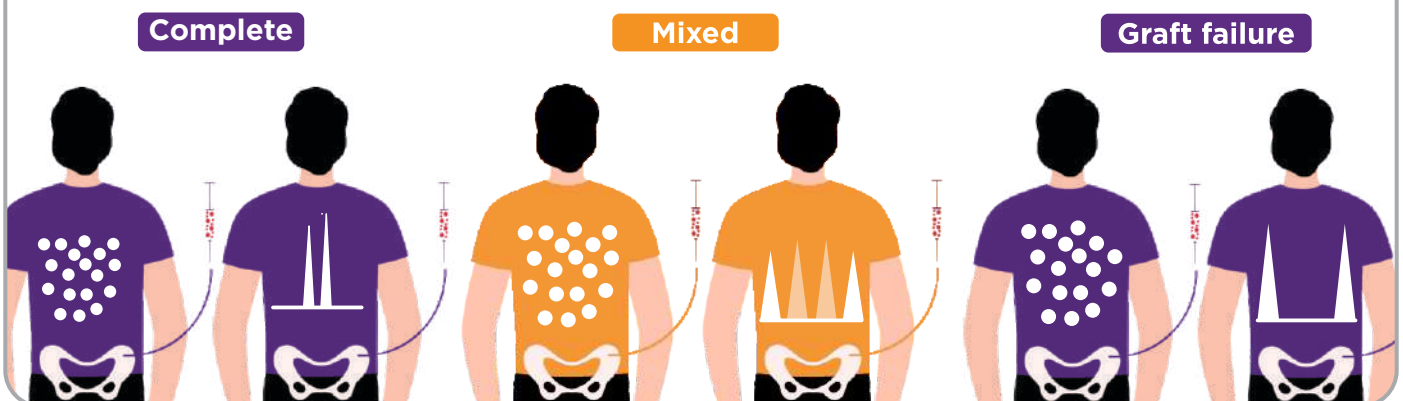
Why Chimerism Testing ?

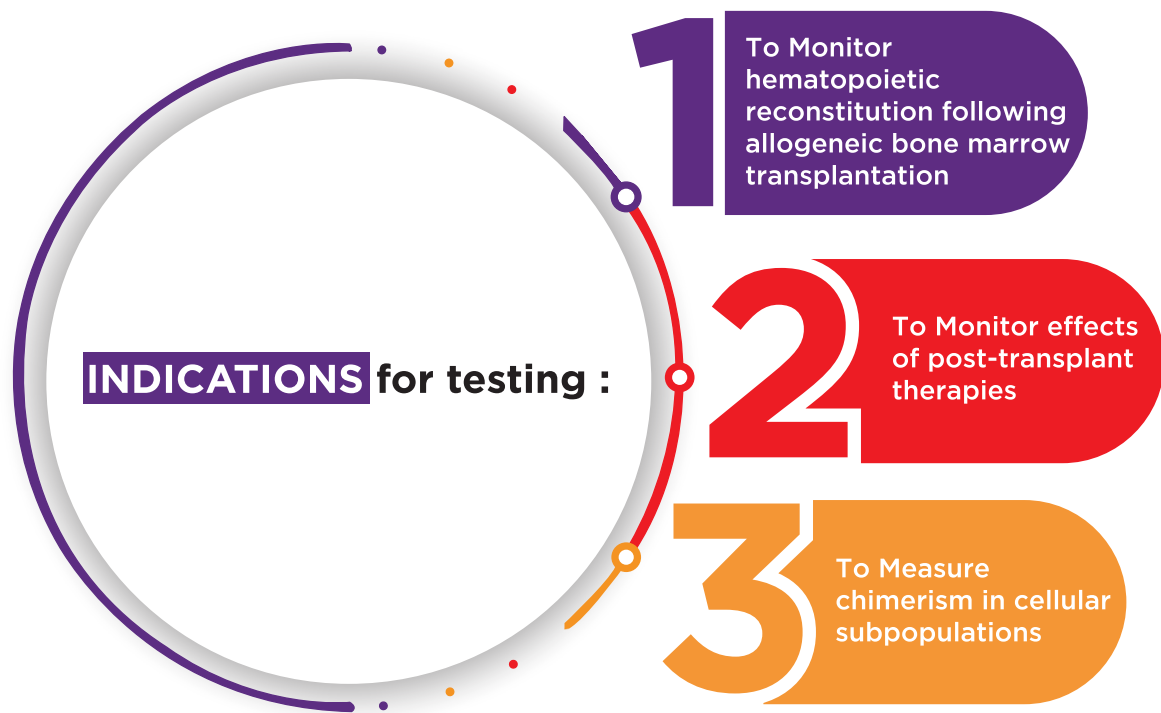
Transplant monitoring by measuring the relative ratio of the recipient and the donor cell population in the recipient's post transplant samples

Before Transplant



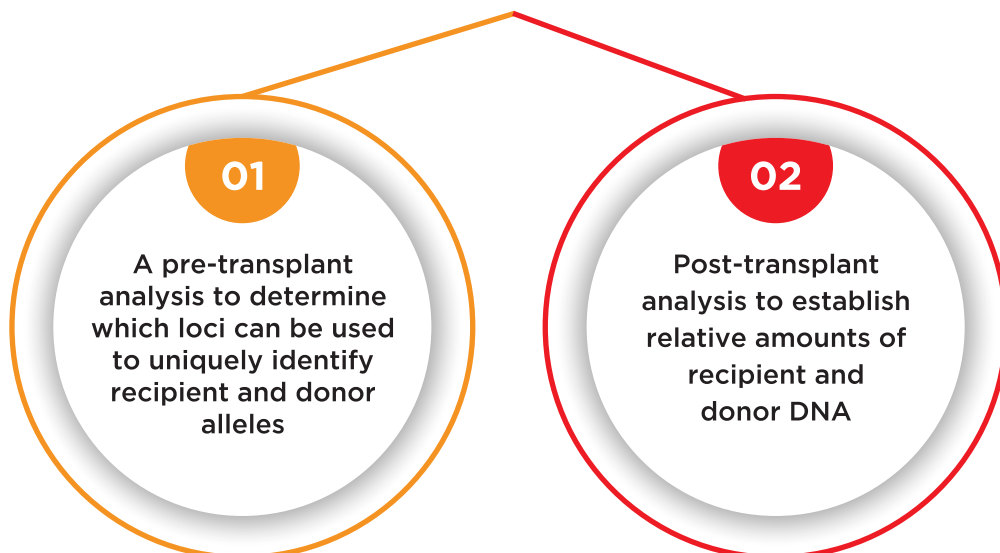
After Transplant





Test Method

This test is performed in two parts :



- ▶ PCR amplification and fragment length analysis by electrophoresis of the appropriate informative loci identified in pre-transplant samples enables relative quantification of recipient and donor cells.
- ▶ Chimerism can be done from whole blood, bone marrow, and enriched cell subsets that are prepared using magnetic beads. The enriched cells are then used in chimerism testing to provide deeper analysis of transplant dynamics. Flow cytometry is used to analyze purity and population/yield of enriched cells.

Limitations:

Pre-transplant analysis must be performed on donor and recipient samples before post-transplant analysis.

Reporting of results:

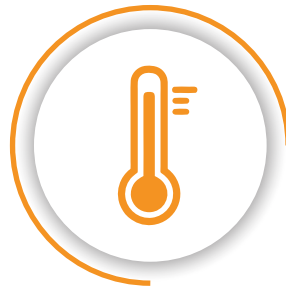
The average % donor value is reported rounded to the nearest integer. SD & CV is also reported for each sample. Purity of the cell subset is usually reported if enrichment is ordered.

Specimen requirements:

Pre-transplant sample of (Patient/Recipient and donor both)



5 ml whole blood in
anticoagulants EDTA



Sample should be stored and
transported at ambient
temperature (15-25°C)

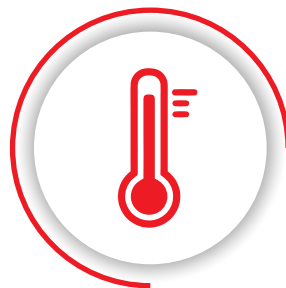


Ice packs should be used for
transportation of samples in
summers, especially in the
areas where temperatures
can reach > 35°C

Post-transplant sample of (Patient/Recipient only)



5 ml whole blood
or marrow in
anticoagulants
EDTA.



Sample should be stored and
transported at ambient
temperature (15-25°C)



Ice packs should be used for
transportation of samples in
summers, especially in the
areas where temperatures
can reach > 35°C

**Turnaround Time: 5 working day for routine samples
3 working days for urgent samples**

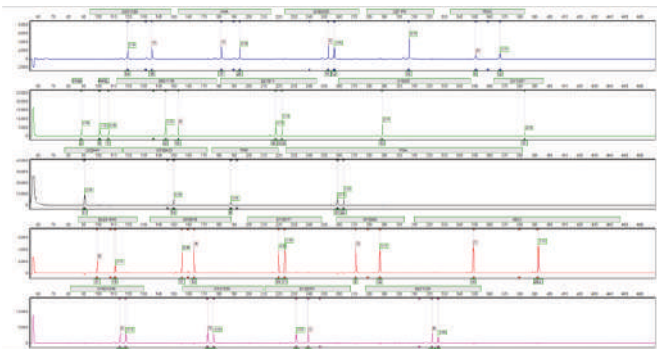
Methodology :

- ▶ Specimens are analyzed by PCR followed by capillary electrophoresis using 21 autosomal markers (D8S1179, D21S11, D7S820, CSF1PO, D3S1358, THO1, D13S317, D16S539, D2S1338, D19S433, vWA, TPOX, D8S1179, D22S1045, SE33, D10S1248, D1S1656, D12S391, D18S51, D5S818, and FGA) and three gender markers Yindel, DYS391 and AMEL (amelogenin)
- ▶ These loci exhibit alleles that may differ in length between individuals
- ▶ After confirming the presence of expected markers, the most informative STR markers are used to differentiate and quantify donor and recipient components in the post-transplant sample.
- ▶ The patient's post-transplant STR profile peaks are compared to the pre-transplant STR peaks of patient and donor to calculate the % donor or % recipient chimerism.

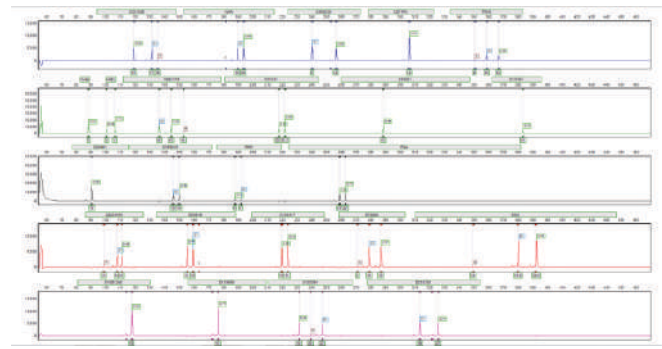
Report format showing STR profiles for Pre and Post Transplant Samples

Pre-Post Transplant Engraftment Monitoring

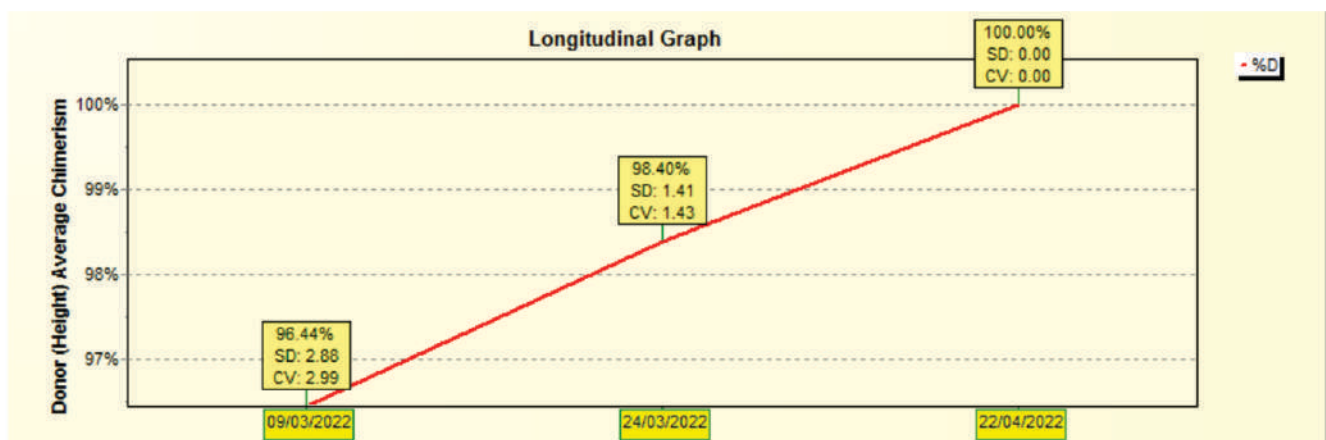
Pre -Transplant



Post - Transplant



Post - Transplant



Report format showing STR profiles for Pre and Post Transplant Samples

No.	Marker Name	%D CHM	LE	ME	Ignored
1	D3S1358	100.00%	0.00%	NAN	No
2	vWA	NI	NI	NI	Yes(Auto)
3	D16S539	NI	NI	NI	Yes(SAI)
4	CSF1PO	NI	NI	NI	Yes(Auto)
5	TPOX	NI	NI	NI	Yes(Auto)
6	Yindel	NI	NI	NI	Yes(Auto)
7	AMEL	NI	NI	NI	Yes(Auto)
8	D8S1179	NI	NI	NI	Yes(Auto)
9	D21S11	NI	NI	NI	Yes(Auto)
10	D18S51	100.00%	0.00%	0.00%	No
11	DYS391	NI	NI	NI	Yes(Auto)
12	D2S441	100.00%	0.00%	0.00%	No
13	D19S433	NI	NI	NI	Yes(Auto)
14	Th01	100.00%	0.00%	NAN	No
15	FGA	NI	NI	NI	Yes(Auto)
16	D22S1045	ϕ	2.12%	NAN	Yes(User)
17	D5S818	NI	NI	NI	Yes(Auto)
18	D13S317	100.00%	0.00%	0.00%	No
19	D7S820	ϕ	0.35%	NAN	Yes(User)
20	SE33	NI	NI	NI	Yes(Auto)
21	D10S1248	NI	NI	NI	Yes(Auto)
22	D1S1656	100.00%	0.00%	NAN	No
23	D12S391	NI	NI	NI	Yes(Auto)
24	D2S1338	NI	NI	NI	Yes(Auto)

%D CHM

Average Chimerism

100.00%

Coefficient of Variation

0.00%

St.Dev

0

Number of informative Loci

4

* NI- Non Informative
LE - Locus Error
ME - Measurement Error

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