AlloSeq™ HCT

Jen R.,
Stem Cell and Double Lung
Transplant Recipient

Revolutionizing Chimerism Monitoring

THE LATEST INNOVATION IN CHIMERISM TESTING OFFERS STREAMLINED WORKFLOW WITH BEST-IN-CLASS SENSITIVITY

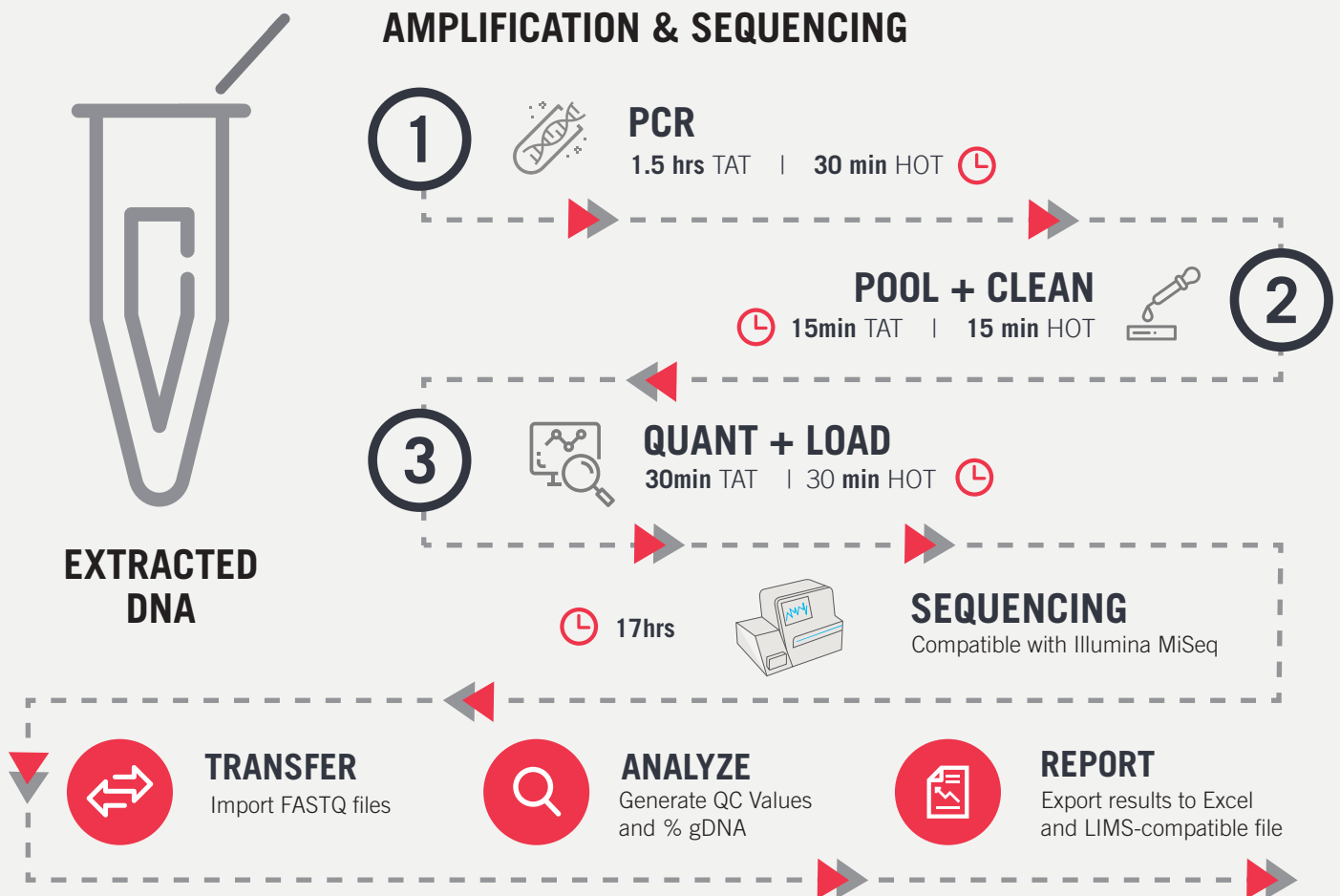Chimerism changes after hematopoietic cell transplant can be an early indication of relapse*

Early detection can lead to early intervention

CareDx®

What is AlloSeq HCT?

- A **NGS based chimerism testing solution** that is able to determine the relative contribution of up to 3 genomes in a single sample i.e. up to two donors per recipient

- A kit based test that offers high quality data with a recommended input of **10 ng of gDNA** and up to **24 samples per batch**

- A one-step multiplex assay that utilizes **202 SNPs** across all autosomal chromosomes to differentiate between recipient and donor(s) gDNA

- A **highly sensitive, scalable assay** with time-saving automated analysis software

AlloSeq HCT is a simple and fast assay with **minimal hands-on time**.

gDNA Sample to Report in Less than 24 hours

EXTRACTED DNA

AMPLIFICATION & SEQUENCING

1 PCR
1.5 hrs TAT | 30 min HOT

2 POOL + CLEAN
15min TAT | 15 min HOT

3 QUANT + LOAD
30min TAT | 30 min HOT

17hrs

SEQUENCING
Compatible with Illumina MiSeq

TRANSFER
Import FASTQ files

ANALYZE
Generate QC Values and % gDNA

REPORT
Export results to Excel and LIMS-compatible file

*References for early rejection
- Rashef et al BBMT 2014;20:1758–66
- Tang et al BBMT 2014;20:1139:1144

For Research Use Only. Not for use in diagnostic procedures.

*HOT: Hands-on Time   *TAT: Turn around time

AlloSeq HCT offers **accurate** and **precise results**

72 DNA mixtures simulating post-transplant samples demonstrate test dynamic range of 0.1% - 99.9%
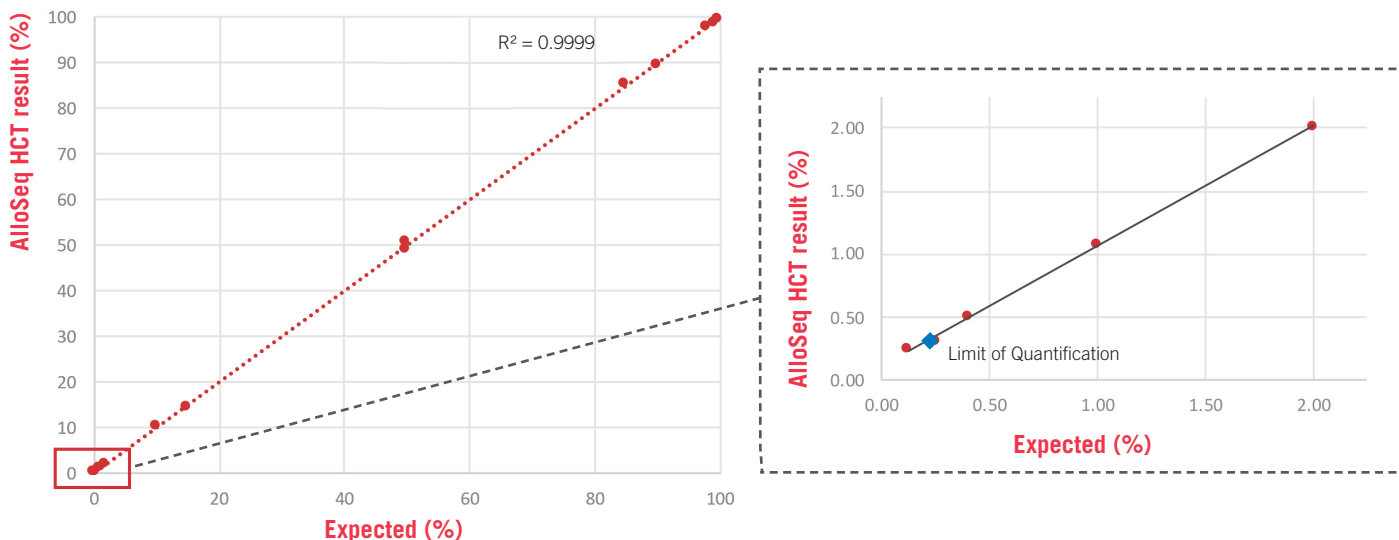
AlloSeq HCT accuracy was measured against expected using artificially mixed gDNA samples extracted from fresh whole blood. 72 data points were generated achieving signal linearity with a correlation and slope close to 1. The Limit of Quantification (LOQ) obtained is shown and marked on the graph (for post transplant samples with a single donor)

AlloSeq HCT is reproducible with **high quality data**

Internal and external validation produces reproducible and precise data

TABLE 1: Internal Validation at CareDx

Expected Fraction	0.4%	1%	10%	50%	85%	98%
Observed Fraction	0.5%	1.1%	10.5%	50.7%	85.2%	98%
Coefficient of Variation	8.6%	7.7%	2.1%	0.2%	0.5%	0.1%
Sample Number (N)	20	12	11	3	3	4

TABLE 2: External Validation

Expected Fraction	5%	50%	95%
Observed Fraction	4.8%	48.2%	94.7%
Coefficient of Variation	4.8%	0.5%	0.2%
Sample Number (N)	3	3	3

Table 1 & 2 represent the AlloSeq HCT average result for artificially mixed samples across a number of technical replicates. Table 2 shows validation results at an external lab confirming the reproducibility obtained at CareDx.

AlloSeq HCT provides easy and **fast results** with **automated analysis**.

The Windows based software is user-friendly and LIMS compatible.

All samples are reported on a single screen

Post-transplant samples

SAMPLE NAME	ANALYSIS DATE	DNA TYPE	SAMPLE QUALITY	RECIPIENT DNA	DONOR-1 DNA	DONOR-2 DNA	DETAILS VIEW
E10R1	NA	gDNA	Pass	0.83%	8.89%	90.27%	👁
E10R10	NA	gDNA	Pass	1.01%	8.58%	90.41%	👁
E10R11	NA	gDNA	Pass	0.89%	8.85%	90.26%	👁

Recipient-only

SAMPLE NAME	ANALYSIS DATE	DNA TYPE	SAMPLE QUALITY	DETAILS VIEW
Blood3R5	2019-11-21	gDNA	Pass	👁

Donor-only

SAMPLE NAME	ANALYSIS DATE	DNA TYPE	SAMPLE QUALITY	DETAILS VIEW
Blood1R6	2019-11-21	gDNA	Pass	👁
Blood2R4	2019-11-21	gDNA	Pass	👁

"Detailed report by sample can be seen by clicking on "Details view"

Detailed % DNA display for each sample

Result Details

AlloSeq HCT Sample Analysis Report

Analysis output

	RECIPIENT DNA	DONOR-1 DNA	DONOR-2 DNA
	0.83%	**8.89%**	**90.27%**
	[0.66%-1.00%]	[8.63%-9.15%]	[90.02%-90.52%]

Sample info

Sample name	E10R1
Source type	Post-transplant

Analysis inputs

DNA type	gDNA
DNA amount (ng)	10ng
Recipient Sample	Blood3R5
Donor1 Sample	Blood2R4
Donor2 Sample	Blood1R6

Analysis information

Analysis date	2019-11-21 15:11:41
Worker version	1.0.0
Pipeline version	1.2.5.6-hct
Operator	XDXINC\cegidio

Actions

Delete Analysis Results | Generate Test Report PDF
Send Results to PDF | View Longitudinal Database

Sample quality: **Pass**

Mean Coverage: **Pass**
3252 Threshold: 500

Uniformity: **Pass**
90% Threshold: 75%

Loci passing filter: **Pass**
195 Threshold: 186

Loci within range: NA
Recipient-only sample filter: **Pass**
Donor-only sample filter: **Pass,Pass**

Other sample metrics

Informative Loci: 124, 121

Loci removed from analysis

Low coverage	0
Multiallelic	0
Loci removed from recipient-only and/or donor-only sample(s)	7

AlloSeq HCT

PRODUCT	PRODUCT NUMBER	DESCRIPTION
AlloSeq® HCT	ASHCT.1(24)	Includes all the reagents required to make 24 NGS libraries

For Research Use Only. Not for use in diagnostic procedures.

Visit www.caredxinc.com/alloseq-hct for more information
For inquiries, contact your CareDx representative or reach out to us:

Phone numbers:
Americas – orders-US@caredx.com
EMEA – orders-at@caredx.com
Nordics – orders-aus@caredx.com
APAC – orders-se@caredx.com

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