

<b>Product name:</b>	AlloSeq HCT
<b>Product code:</b>	ASHCT.1(96)
<b>Lot number:</b>	23-1360
<b>Expiry date:</b>	2025-09-13
<b>Number of tests:</b>	96
<b>Storage:</b>	
Box 1 and 2:	-15°C to -25°C
Box 3:	2°C to 8°C
Product Insert:	Room temperature
<b>Kit contents:</b>	This product contains tests that enables relative quantification of genetic chimerism in genomic DNA (gDNA) samples for research use only.
<b>Warnings and Precautions</b>	Through the CareDx Pty Ltd risk management process, all risks have been mitigated to an acceptable limit. Instructions for Use must be followed to prevent hazardous use scenarios. Hazardous materials are present in this kit. Please consult the Safety Data Sheets and take all required precautions in handling and disposal.

Changes compared to the previous product batch:
IFU088 & IFU092 - Instructions added to section 2.3, steps 4,8,12 & 20 to briefly spin down the tube content prior to placing on the magnet.

The following documents, and their translations, may be downloaded from <https://www.caredx.com/lab-products/>

- IFU088\_AlloSeq HCT IFU RUO (version 5.0, issued November 2022)
- IFU092\_AlloSeq HCT 96 IFU RUO (version 4.0, issued November 2022)
- TEC513\_AlloSeq HCT Safety Data Sheet (version 3.0, issued December 2021)

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CareDx Pty Ltd

CareDx Pty Ltd  
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AUSTRALIA

## CERTIFICATE OF ANALYSIS

CERTIFICATE NUMBER: 23-0045

### MANUFACTURER AND TESTING LABORATORY:

CareDx Pty Ltd  
20 Collie Street  
Fremantle WA 6160  
AUSTRALIA

### PRODUCT INFORMATION

Product Name: AlloSeq HCT  
Product Code: ASHCT.1(96)  
Batch number: 23-1360

Kit size: 96  
Expiry date: 2025-09-13

### TESTING PROCEDURE

A panel of DNA samples (of known genetic mixtures) was used to assess the performance on a single kit from this batch against defined acceptance criteria.

### TEST RESULTS

TEST	ACCEPTANCE CRITERIA	RESULT
Locus Count	$\geq 186$	PASS
Uniformity	$\geq 0.75$	PASS
Mean Coverage	$\geq 500$	PASS
Recipient % DNA	Within limits	PASS
Donor 1 % DNA	Within limits	PASS
Donor 2 % DNA	Within limits	PASS

### CONCLUSION

Compliance with acceptance criteria? **YES** **NO**

### CERTIFICATION

I hereby certify that the testing was performed according to the company's standard operating procedures. I also certify that the results obtained were reviewed and released by myself prior to the issue of this certificate.

Signed: *Shany*

Name: *Loni Longley*

Position: *QA Associate*

Date of Issue: *12 Oct 23*