

Product name:	AlloSeq HCT
Product code:	ASHCT.1(24)
Lot number:	23-1320
Expiry date:	2025-09-13
Number of tests:	24
Storage:	
Box 1 and 2:	-15°C to -25°C
Box 3:	2°C to 8°C
Product Insert:	Room temperature
Kit contents:	This product contains tests that enables relative quantification of genetic chimerism in genomic DNA (gDNA) samples for research use only.
Warnings and Precautions	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)

ADDRESSES:**Manufacturer:**

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CareDx Pty Ltd

CareDx Pty Ltd
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AUSTRALIA

CERTIFICATE OF ANALYSIS

CERTIFICATE NUMBER: 23-0043

MANUFACTURER AND TESTING LABORATORY:

CareDx Pty Ltd
20 Collie Street
Fremantle WA 6160
AUSTRALIA

PRODUCT INFORMATION

Product Name: AlloSeq HCT
Product Code: ASHCT.1(24)
Batch number: 23-1320

Kit size: 24
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	≥ 186	PASS
Uniformity	≥ 0.75	PASS
Mean Coverage	≥ 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: *Lorie Langley*

Name: *Lorie Langley*

Position: *QA Associate*

Date of Issue: *11 Oct 23*